WHAT IS PSORIASIS?

Psoriasis is pronounced sore-EYE-ah-sis. It is an autoimmune disease, meaning that certain triggers cause the immune system to go into overdrive. This hyperactivity can result in painful, scaly, inflamed patches of skin (plaques) that can interfere with functions as basic as walking and sleeping.

Psoriasis is a chronic (persistent) condition that is genetic in origin. It is not contagious, but it is lifelong. Psoriasis is the most common autoimmune disease in the United States, affecting approximately 7.5 million people.

Symptoms often appear sometime between the ages of 15 and 25, but the condition can develop at any age. Psoriasis occurs nearly equally in women and men and across all socioeconomic groups. It also is present in all racial groups, but at varying rates.

Though psoriasis varies from person to person, both in severity and how it responds to treatment, it’s almost always a game-changer: limiting people’s activities, plunging them into depression, and raising their risk for comorbidities (related illnesses) such as diabetes and heart disease.

People with psoriasis may deal on a daily basis with pain and itch — as well as low self-esteem, relationship problems, and feeling stigmatized because of how they look.

Psoriasis is incurable, but there are a growing number of ways to treat it and manage the symptoms. Studies continue to show that treating the disease is your best bet to improve your quality of life and reduce the risk of developing comorbidities.

WHAT IS PSORIATIC ARTHRITIS?

Psoriatic arthritis is a chronic, inflammatory disease of the joints and the places where tendons and ligaments connect to bone. This can result in pain, fatigue, stiffness and swelling. People with psoriatic arthritis may find many of their usual activities restricted by the disease. Like psoriasis, psoriatic arthritis is not contagious. It’s also lifelong.

About a third of all of people with psoriasis end up with psoriatic arthritis, but the severity of one does not dictate the severity of the other. Psoriatic arthritis can develop at any age, though it commonly appears between the ages of 30 and 50. For most people with this condition, it appears about 10 years after the onset of psoriasis.

There is no specific test for diagnosing psoriatic arthritis. A diagnosis is based mostly on symptoms.

These are among the most common:

- Stiffness, pain, throbbing, swelling and tenderness in one or more joints
- Tenderness, pain and swelling over tendons
- Swollen fingers and toes
- Reduced range of motion
- Morning stiffness
- Nail changes: the nail separates from the nail bed, becomes pitted, or mimics fungus infections
- Redness and pain of the eye, such as conjunctivitis
- Generalized fatigue

It’s extremely important to talk to your health care provider about these symptoms, especially if you already have psoriasis or if any of your family members have psoriasis or psoriatic arthritis. Left untreated, psoriatic arthritis can cause permanent joint damage. Though there is no cure, there are a growing range of treatments available that can help you deal with pain, protect your joints and preserve your range of motion.
SYSTEMIC MEDICATIONS

Systemic medications are prescription drugs that affect the entire body. Most people who use them have moderate to severe psoriasis and/or psoriatic arthritis. Systemic medications are also used by people who are not responsive to or are unable to use topical medications or ultraviolet (UV) light treatment.

These drugs are taken by mouth in liquid or pill form or given by injection into the skin or muscle or through intravenous (IV) infusion. We’ll cover these systemic medications:

- Traditional systemics, which are created by combining chemicals and have been used for many years
- Biologics, a newer class of drugs that are made from human or animal proteins
- Newer oral treatments that target a particular enzyme related to psoriatic disease

TRADITIONAL SYSTEMICS

Cyclosporine

What is it and how does it work?

Cyclosporine was first used to help prevent organ rejection in organ transplant patients. In 1997, the U.S. Food and Drug Administration (FDA) approved Neoral (one brand name for cyclosporine) for treatment of psoriasis.

How is it used?

Cyclosporine is used for adults with severe psoriasis and otherwise normal immune systems. It suppresses the immune system and stops the activity of certain immune cells, which slows the growth of skin cells.

Cyclosporine is taken daily by mouth and is available as a capsule or a liquid. The liquid form must be diluted for use, preferably mixed with room temperature orange or apple juice. (But not grapefruit juice. See page 7 for more on drug interactions.) It should be taken on a consistent daily schedule.

Cyclosporine can provide rapid relief from psoriasis symptoms, sometimes in as little as two weeks, particularly with larger doses. However, it may take three to four months to reach a complete level of control.

Transplant patients have used cyclosporine for many years. There is less certainty about its long-term use for treatment of psoriasis. The FDA recommends the drug not be used for more than one year because of potential kidney damage.

However, there are no specific guidelines for how long people should stay off cyclosporine if they stop and then resume treatment. Some doctors may prescribe the drug for more than one year, while others try to limit total lifetime use to one year.

Who should not take cyclosporine?

- People whose immune systems are compromised (for example, anyone with lymphoma or HIV infection, or anyone receiving other immune-suppressing drugs)
- Patients with active, serious infections
- Women who are breast-feeding
- People with abnormal kidney function
- People with uncontrollable high blood pressure
- People with cancer or a history of cancer (other than basal or squamous cell skin cancers)
- People who are undergoing radiation treatment
- People with severe gout

What are the risks?

Your risk of developing skin cancer when taking cyclosporine increases if you’ve been treated with any of the following:
People taking cyclosporine are also at increased risk of developing lymphomas and cancers not related to the skin.

Renal dysfunction, including kidney damage, is another potential risk and increases with length of time and amount of cyclosporine taken. This risk is further increased in people with existing kidney damage. Your health care provider will monitor your kidney function with blood tests before and during treatment with cyclosporine. Your blood pressure must be monitored as well, because it’s possible to develop hypertension while on this medication.

Vaccinations may be less effective while taking cyclosporine. Talk to your doctor if you plan to get a vaccination.

In general, women are advised not to become pregnant while taking cyclosporine. However, your health care provider may prescribe it if the benefits outweigh the personal risks.

What are the potential drug interactions?

Your health care provider should always be aware of any medications, treatments or dietary supplements you are using. Many medications interact with the drugs described in this booklet.

Many medications interact with cyclosporine, including certain antibiotics, anti-inflammatories, antifungals, gastrointestinal agents, calcium channel blockers and anticonvulsants.

Over-the-counter (OTC) medications such as aspirin and ibuprofen can also interact with cyclosporine. These interactions can affect the metabolism of the drug, causing you to have either too much or too little of the drug in your bloodstream.

Avoid drinking grapefruit juice or eating grapefruit while taking cyclosporine. Grapefruit can increase the level of the drug in your bloodstream. Eating a potassium-rich diet while on cyclosporine can raise your potassium too much. Talk with your health care provider about the amount of potassium-rich foods such as bananas, tomatoes, raisins and carrots that is advisable for you while taking cyclosporine.

St. John's wort, a popular dietary supplement used for treating depression, can reduce the blood level of cyclosporine in transplant patients. It is not clear if the dose of cyclosporine used in treating psoriasis would be affected by taking St. John’s wort. This is another conversation for you and your health care provider.

Can cyclosporine be used along with other treatments?

You can use cyclosporine along with the topical vitamin D drugs, Dovonex and Vectical (generic names calcipotriene and calcitriol), as well as topical corticosteroids. All of these topical treatments are safe and effective for severe chronic plaque psoriasis. If using a topical plus cyclosporine leads to improvement, you may be able to lower your dose of cyclosporine. This
lessens the risk of side effects. Your health care provider may recommend alternating cyclosporine with other forms of treatment to manage psoriasis better. This is called rotational therapy.

Normally, doctors do not prescribe cyclosporine for people using PUVA or UVB therapies or methotrexate or other immunosuppressive agents. Cyclosporine can increase the skin’s sensitivity to the sun, so remember to protect your skin on sunny days.

**Methotrexate**

**What is it and how does it work?**

Methotrexate is in a class of medications known as antimetabolites. It was initially used to treat cancer. Methotrexate was found to be effective in clearing psoriasis in the 1950s and was approved for this use by the FDA in the 1970s. It is usually sold as a generic. Methotrexate is prescribed for adults with severe psoriasis or with psoriatic arthritis. The doses administered for psoriasis and psoriatic arthritis are considerably lower than those given for cancer.

**How is it used?**

Methotrexate is taken once a week, either by mouth or by injection. It is usually taken orally, either in pill or liquid form. The liquid form may be mixed with fruit juice. It can be taken in a single dose or in three doses taken at 12-hour intervals over a period of 24 hours.

Sometimes a test dose of methotrexate is given first to see if a person tolerates the drug. If it is, the dosage is increased gradually to achieve clearance. Once the skin is clear, the dose may be gradually reduced to the lowest level capable of maintaining reasonable improvement.

However, some people may choose not to taper off the medication if it is effective and well tolerated. If a few stubborn lesions remain, a doctor will usually not increase the dose of methotrexate. Instead, another treatment, such as a topical, may be added.

Improvement from methotrexate usually begins within three to six weeks of starting the drug. It may take up to six months to achieve the highest degree of improvement.

**Who should not take methotrexate?**

- People with alcoholism, alcoholic liver disease or other chronic liver diseases such as cirrhosis and hepatitis B and C
- People with immunodeficiency syndromes
- Pregnant or nursing women
- Women (or their male partners) planning a pregnancy
- People with active peptic ulcers
- People with significant liver or kidney abnormalities
- People with an active infectious disease

People with pre-existing blood problems such as underdevelopment of bone marrow, low white blood cell count, low platelets or significant anemia should use methotrexate with caution.

**What are the risks?**

The main risk of long-term methotrexate treatment is liver damage.

A small number of people, estimated to be 1 in 200, develop reversible liver scarring. After they stop taking methotrexate, their liver will return to normal. This is a potential risk after an individual has reached a lifetime accumulation of 1.5 grams (g) of methotrexate. How long it takes an individual to reach 1.5 g depends on several factors, including his/her treatment schedule and whether she/he takes any breaks from the drug.

In rare instances, some people develop irreversible cirrhosis. The risk can be minimized by monitoring for liver toxicity at regular intervals and by avoiding other medications that are known to be toxic to the liver.

In people with a risk factor for liver disease,
doctors may perform a liver biopsy to test for liver damage or consult with a specialist once a lifetime accumulation of anywhere from 1.5 g to 3 g has been reached. In a biopsy, a thin needle is inserted through the skin to obtain a small sample of liver tissue. If significant liver damage is shown, methotrexate is usually discontinued.

A liver biopsy may need to be repeated at regular intervals. However, some health care providers do not recommend biopsies for patients without elevated risks for liver damage.

The risk of liver damage increases if a person drinks alcohol, has abnormal kidney function, is obese, has diabetes or has had prior liver disease. Ask your doctor about the safe use of alcoholic beverages while you are taking methotrexate.

People who take methotrexate need regular blood tests to ensure that the drug is being safely processed by the body, and that the liver, blood or bone marrow is not negatively affected. Methotrexate can cause a reduced white blood cell count, which can increase the risk of infection.

Regarding pregnancy: Studies have demonstrated harmful effects of methotrexate on fetal development.

- Men should be off methotrexate for at least three months before a couple tries to conceive.
- Women should be off methotrexate for at least four months before trying to conceive.

What are the possible side effects?

- Nausea
- Tiredness
- Difficulty sleeping
- Lightheadedness
- Mouth ulcers
- Vomiting
- Headache
- Easy bruising and bleeding
- Fever
- Diarrhea with blood in the stool
- Chills
- Sensitivity to sunlight
- Burning sensation in lesions
- Hair loss

These side effects are generally manageable with careful monitoring and patient education.

However, severe nausea or mouth ulcers can indicate that the dose is too high. In rare instances, some serious side effects may occur years after the drug is used, including certain types of cancer (such as lymphoma) and bone marrow toxicity.

Taking folic acid can decrease the severity of side effects of methotrexate during treatment. Talk with your health care provider about recommendations for folic acid supplements.

What are the potential drug interactions?

Some OTC medications for inflammation or pain (including aspirin and ibuprofen) may increase the side effects of methotrexate.

Some oral antibiotics can interfere with the absorption of methotrexate. Penicillin can reduce clearance of the drug from the kidneys. Talk to your health care provider before taking any of these drugs while taking methotrexate.

Drinking alcohol while on a course of methotrexate is not recommended because it increases the chance of liver damage. Drugs containing trimethoprim and sulfamethoxazole (such as Septra or Bactrim) must also be avoided. The interaction of these drugs and methotrexate can be fatal.

On rare occasions, sensitivity to light can occur even when methotrexate is taken several days after exposure to ultraviolet light. This is called a “sunnburn recall.”

Can it be used with other treatments?

Methotrexate is sometimes rotated with other treatments such as PUVA or UVB, Soriatane (acitretin), cyclosporine or a biologic. Rotation may decrease side effects.

Methotrexate can be used with PUVA or UVB to
reduce the amount of ultraviolet light needed to clear the skin. In unresponsive cases of generalized pustular psoriasis, methotrexate has been used with Soriatane. Methotrexate has also been used with biologics to prevent resistance and increase response to both medications.

**Soriatane (acitretin)**

**What is it and how does it work?**

Soriatane (acitretin) is an oral retinoid, which is a synthetic form of vitamin A. Synthetic retinoids were approved in the U.S. in the 1980s. Soriatane is the only oral retinoid approved by the FDA specifically for treating psoriasis. Isotretinoin, another oral retinoid, is sometimes used instead of Soriatane to treat psoriasis (see page 16 for more about isotretinoin).

The exact way that Soriatane works to control psoriasis is unknown. In general, retinoids affect how cells regulate their behavior. Retinoids help control the multiplication of cells, including the speed with which skin cells grow and shed, which increases in psoriasis.

**How is it used?**

Soriatane comes in 10 milligram (mg), 17.5 mg and 25 mg capsules. The prescribed dose is taken once a day, preferably with food. Several factors determine the correct dosage for each person, including the type of psoriasis.

The dosage may be reduced or even stopped after symptoms improve, for example, if lesions have cleared significantly. When lesions or other symptoms reappear, the drug may be restarted.

Soriatane tends to work slowly for plaque psoriasis. Psoriasis may worsen before clearing begins. After eight to 16 weeks of treatment, the skin lesions usually improve. It may take up to six months for the drug to reach its peak effect. Soriatane rarely clears psoriasis alone and works best in combination with phototherapy.

Soriatane is approved for use in adults with severe psoriasis. The Soriatane label supports use of the drug for plaque, guttate, pustular, erythrodermic and palmoplantar psoriasis. Soriatane is helpful in people with psoriasis who are prone to skin cancers such as squamous cell carcinoma.

**Who should not take Soriatane?**

- Pregnant women or women who might become pregnant during treatment
- Women who are breast-feeding
- People with severe liver or kidney disease
- People who repeatedly show a high level of fat in the blood that cannot be controlled by medications
- People who are allergic to or have hypersensitivity to retinoids

**What are the risks?**

The most serious risk with Soriatane is that of severe birth defects in developing fetuses if a woman has the drug in her body during pregnancy. Soriatane can remain in the body for many months, so it should not be taken for three years before pregnancy.

Because of the risk of birth defects, women in their childbearing years must have two negative pregnancy tests before starting Soriatane. They must use two effective forms of birth control at least one month before beginning treatment, while on the drug and for three years after stopping treatment. Women who become pregnant during the three years following treatment should seek the advice of a doctor who specializes in high-risk pregnancies.

Progestin-only birth control pills may not work while taking Soriatane, so women should not use them as a primary form of birth control.

People should not donate blood during treatment and for three years after stopping treatment. Donated blood could expose pregnant women to Soriatane.
What are the possible side effects?

- Hair loss
- Chapped lips and dry mouth
- Dry skin and dry eyes
- Bleeding gums and nose bleeds
- Increased sensitivity to sunlight
- Peeling fingertips and nail changes
- "Sticky" skin sensation
- Changes in blood fat level
- Depression
- Aggressive thoughts or thoughts of self-harm
- Headache
- Joint pain
- Decreased night vision
- Elevated liver enzymes

These side effects, and others, seem to be dosage-dependent. They tend to go away after stopping the medication or reducing the dosage.

What are the potential drug interactions?

When taking Soriatane, avoid dietary supplements that have vitamin A. Soriatane is related to vitamin A, and taking vitamin A could add to any side effects Soriatane might cause.

Women of childbearing age who use Soriatane must not drink or eat anything containing alcohol during treatment and for two months after treatment is stopped. Consuming alcohol can cause Soriatane to stay in your body longer, which increases the risk of birth defects if a woman becomes pregnant.

Soriatane can reduce the effectiveness of phenytoin, a common drug for epilepsy, when taken concurrently.

Soriatane should not be taken concurrently with tetracycline, an antibiotic, since both medications can cause increased pressure on the brain, which can have serious consequences.

Can it be used with other treatments?

Soriatane is most effective for treating psoriasis when used in combination with phototherapy rather than by itself. Combination therapy can speed clearing and help reduce the amount of phototherapy needed to clear symptoms. This reduces the risks and side effects of both treatments.

Soriatane is sometimes used with the biologic drugs Enbrel (etanercept) and Remicade (infliximab) to achieve clearing of psoriasis. Soriatane may also be prescribed in rotation with other systemic medications, such as cyclosporine or methotrexate.

OTHER SYSTEMIC MEDICATIONS

The following are not approved by the FDA for the treatment of psoriasis or psoriatic arthritis. However, some doctors prescribe them “off-label”—a common and accepted medical practice.

Antimalarial therapy

Sometimes used to treat psoriatic arthritis. Certain antimalarial drugs may trigger psoriasis symptoms in some people.

Hydrea (hydroxyurea)

HYDREA is an oral cancer medication that, in the late 1960s, was found to be effective for treating psoriasis. Although not as effective as methotrexate, it is less likely to cause liver damage with long-term use. While fewer people will have an acceptable response than with methotrexate, Hydrea can produce significant improvement in stable plaque psoriasis in about half of those who tolerate it.
The major side effect of Hydrea is bone marrow toxicity. If this develops, it can occur quite rapidly, so close monitoring is important, especially in the first several months. Long-term use has been associated with skin cancer.

**Isotretinoin**

**ISOTRETINOIN** is an oral retinoid (like Soriatane) that was approved as a treatment for severe cystic acne in 1982. Some doctors have used it successfully to treat pustular psoriasis. Generally, it is not as effective as Soriatane for plaque psoriasis.

Isotretinoin has many side effects similar to Soriatane (see discussion of Soriatane on page 12). The most common side effects are eye and lip dryness and nosebleeds. Bone spurs and hair loss occur to a lesser degree. Isotretinoin leaves the body much faster than Soriatane, and some doctors consider it safer for women in their childbearing years.

However, it also can cause severe birth defects if a woman becomes pregnant while the drug is in her system. Women in this category who take isotretinoin should use reliable birth control one month before treatment, during treatment and for at least one month after stopping treatment.

**Cellcept**

**(mycophenolate mofetil)**

**CELLCEPT** has been used to prevent organ transplant rejection. It has also been used for treatment of several inflammatory or autoimmune skin diseases and liver diseases such as hepatitis. It can be used in combination with cyclosporine. Some doctors use it when tapering patients off cyclosporine.

Cellcept can be used as a stand-alone treatment for psoriasis, though many doctors believe that it’s not very effective in this role. Because it can suppress the immune system, people with a compromised immune system shouldn’t take it.

**Nonsteroidal anti-inflammatory drugs (NSAIDs)**

**NSAIDs** can help relieve the pain, swelling and stiffness of psoriatic arthritis. They are available in OTC and prescription strengths. Examples of OTC NSAIDs include aspirin, ibuprofen (Advil, Motrin) and naproxen sodium (Aleve).

If you are taking frequent doses of one of these NSAIDs to control your psoriatic arthritis, you may need to move to prescription-strength medications. Talk to a rheumatologist about the best options to control your symptoms and prevent permanent joint damage.

**Sulfasalazine**

**AZULFIDINE (sulfasalazine)** is a combination of anti-inflammatory and antibiotic is sometimes used to treat psoriatic arthritis. It is generally regarded as being only modestly effective for plaque psoriasis. Many doctors think that methotrexate is more effective than sulfasalazine, but sulfasalazine’s side effects tend to be less dangerous than methotrexate’s.

Trying this medication may be worthwhile for some. However, many people cannot tolerate sulfasalazine because of an allergy to sulfa or because of side effects, including nausea, vomiting and loss of appetite.

**6-thioguanine**

**6-THIOGUANINE** is an oral medication approved for treating certain types of leukemia. It is effective for plaque psoriasis and has been used to treat pustular psoriasis. 6-thioguanine requires close medical supervision to watch for potential severe side effects, including suppression of bone marrow. Most people who use it feel that it works as often and as well as methotrexate.
BIOLOGIC TREATMENTS

A biologic is a drug that comes from living sources, such as human or animal proteins. Biologics have been around for more than 100 years. However, they have been used for just a little over a decade for psoriasis and psoriatic arthritis.

Biologics target proteins known to be involved primarily in the immune system. They are considered to be less likely to affect other organ systems, although their long-term effects are still being evaluated. Biologics block the action of certain immune cells or chemical messengers that play a role in psoriasis and psoriatic arthritis.

Biologics are administered by injection or by IV infusion.

Doctors are most likely to recommend biologics for people with moderate to severe cases of psoriasis and/or psoriatic arthritis who have not responded to other treatments. They offer another option for those who cannot take some medications because of side effects.

Biologics can be very effective in improving psoriasis and psoriatic arthritis. Three drugs—Enbrel, Humira and Remicade—have been shown in clinical trials to decrease progressive joint damage in psoriatic arthritis.

There are currently three types of biologics for treating psoriatic diseases:

1. Tumor necrosis factor-alpha blockers

TUMOR NECROSIS FACTOR ALPHA (TNF-alpha) is a protein called a cytokine—a chemical messenger of the immune system that causes cells to release other proteins that add to the inflammatory process. In psoriasis and psoriatic arthritis, there is excess production of TNF-alpha in the skin or joints. This leads to the rapid growth of skin cells typical of psoriasis, or to the joint inflammation that characterizes psoriatic arthritis. A reduction in TNF-alpha stops the inflammatory cycle of psoriasis and psoriatic arthritis.

Five biologic medications block TNF-alpha:

01. CIMZIA (certolizumab pegol)
   - Patients should be screened for latent tuberculosis first
   - Patients give themselves an injection under the skin every other week
   - Drug is taken continuously to maintain results
   - May reduce the progression of joint damage
   - Occasional blood tests are recommended

02. ENBREL (etanercept)
   - Patients should be screened for latent tuberculosis first
   - Patients give themselves an injection under the skin once or twice a week
   - Drug is taken continuously to maintain results
   - May reduce the progression of joint damage
   - Occasional blood tests are recommended

03. HUMIRA (adalimumab)
   - Patients should be screened for latent tuberculosis first
   - Patients give themselves an injection under the skin, usually every other week
   - Drug is taken continuously to maintain results
   - May reduce the progression of joint damage
   - Occasional blood tests are recommended

04. REMICADE (infliximab)
   - Patients should be screened for latent tuberculosis first
   - Administered by three IV infusions in a doctor’s office during the first six weeks of treatment
   - Later infusions repeated every eight weeks
• Drug is taken continuously to maintain results
• May reduce the progression of joint damage
• Blood tests are recommended on a regular basis

05. SIMPONI (golimumab)
• Patients should be screened for latent tuberculosis first
• Patients give themselves an injection under the skin once per month
• Drug is taken continuously to maintain results
• May reduce the progression of joint damage
• Blood tests are recommended on a regular basis

2. Interleukin 12/23

STELARA (ustekinumab) works by selectively targeting the cytokines interleukin-12 (IL-12) and interleukin-23 (IL-23). These proteins are believed to play a role in psoriasis and psoriatic arthritis. They are also believed to cause excessive numbers of T cells (the immune cells that cause psoriatic disease) to gather. Stelara reduces inflammation and improves psoriatic disease symptoms for many people who take it.

• FDA-approved for treating psoriasis and psoriatic arthritis
• Patients should be screened for latent tuberculosis first
• Given by injection at the doctor’s office or at home on week zero, week four, then every three months
• Drug is taken continuously to maintain results
• May reduce the progression of joint damage
• Blood tests are recommended on a regular basis

3. Interleukin 17-A

COSENTYX (secukinumab) binds to and inhibits a cytokine called interleukin-17A (IL-17A), which is involved in inflammatory and immune responses. It is approved to treat moderate to severe plaque psoriasis. There are elevated levels of IL-17A in psoriatic plaques. By inhibiting cytokines that trigger inflammation, Cosentyx interrupts the inflammatory cycle of psoriasis. This can lead to improvement in symptoms for many people who take it.

• FDA-approved for treating psoriasis
• Patients should be screened for latent tuberculosis first
• Patients give themselves an injection once a week for the first five weeks, then every four weeks thereafter
• Drug is taken continuously to maintain results

What are the risks?

Biologics for psoriasis and psoriatic arthritis are still relatively new and their overall safety is still being evaluated. People considering treatment with biologics should talk with their doctor about the short- and long-term side effects and risks, which should be weighed carefully against the risks of other treatment options.

Because biologics suppress the immune system, people taking them could be at an increased risk of infection. If they notice any sign of an infection, they should contact their doctor right away.

Drugs that suppress the immune system can also increase the risk of some types of cancer. Various studies have looked at a possible link between biologic therapy and lymphomas and skin cancer, but the data are inconclusive. Biologics have not been tested in patients with internal malignancies.

The risks of biologics for pregnant women or developing fetuses have not been studied.
comprehensively. TNF-alpha blockers can be prescribed for a pregnant or nursing woman if the medical need is clear and the doctor and patient make the decision together.

**What are the possible side effects?**

Common side effects for TNF-alpha blockers include:

- Abdominal pain
- Upper-respiratory infections
- Headache
- Flu-like symptoms
- Injection-site reactions (such as swelling, itch or rash) for self-injected biologics

Side effects for IL-12/23 blockers like Stelara include:

- Headache
- Fatigue or tiredness
- Respiratory infections
- Hypersensitivity reactions (such as a rash or hives around the injection site)

Side effects for IL-17A blockers like Cosentyx include:

- Cold symptoms
- Diarrhea
- Upper respiratory infections
- Yeast infections

The side effects of biologics are generally mild and in most cases do not cause people to stop taking the medication. You should tell your health care provider about any side effect that bothers you or does not go away.

**Who should not take biologics?**

- People with active tuberculosis or with a positive TB test who have not been treated with a course of isoniazid as recommended by the American Thoracic Society
- People with multiple sclerosis or a first-degree relative with multiple sclerosis should avoid TNF-alpha blockers
- People with congestive heart failure, including those whose symptoms rank class 3 or 4 in the New York Heart Association classification of heart failure, should also avoid TNF-alpha blockers
- People who have recently received a live vaccine

**Can biologics be used with other treatments?**

All of the current biologics can and have been used with other psoriasis treatments, such as phototherapy or topicals. Enbrel, Humira, Remicade, Stelara and Simponi are safe and effective when taken with methotrexate. Some people have seen success using Soriatane with different biologics.

TNF-alpha blockers should not be used with other biologics such as those used for rheumatoid arthritis. Biologics should be used with caution with other immune-suppressing drugs such as cyclophosphamide, azathioprine and 6-mercaptopurine. Talk to your health care provider about biologics and their use with other treatments.

**ORAL TREATMENT**

**Otezla (apremilast)**

OTEZLA (apremilast) is an oral treatment option for treating psoriasis and psoriatic arthritis. Unlike earlier oral treatments for psoriatic disease, this oral drug selectively targets molecules inside
immune cells. By adjusting the complicated processes of inflammation within the cell, this treatment corrects the overactive immune response that causes inflammation in people with psoriatic disease, leading to improvement in flaking and scaling as well as joint tenderness and swelling.

What is it and how does it work?

Otezla treats psoriasis and psoriatic arthritis by regulating inflammation within the cell. It inhibits an enzyme known as phosphodiesterase 4, or PDE4. PDE4 controls much of the inflammatory action within cells, which can affect the level of inflammation associated with psoriatic disease.

How is it used?

Otezla is available as a 30 mg tablet taken by mouth. Otezla dosing begins with a five-day medication start pack, where the dosage will gradually increase until the recommended dose of 30 mg twice daily is reached. This drug is designed to be taken continuously to maintain improvement.

Who should not take Otezla?

- The safety and effectiveness of Otezla in people under 18 has not been established
- The dosage should be modified or reduced in people with severe renal impairment
- Nursing women should use caution when taking Otezla
- People with a known severe allergic reaction to this treatment or its components should not take Otezla

What are the risks?

In clinical trials, 10 percent of people taking Otezla reported unexplained weight loss of 5 to 10 percent during the trial. It is recommended that people taking Otezla have their weight monitored regularly. Treatment with Otezla is associated with an increase in depression. People experiencing worsening of mood while taking Otezla should contact their doctor.

What are the possible side effects?

In clinical trials, the most common side effects were diarrhea, nausea and headache, which occurred in the first two weeks and tended to lessen with continued treatment.

Can Otezla be used with other treatments?

Yes. In clinical trials, no significant impacts were observed when 30 mg of Otezla was taken with either oral birth control, ketoconazole (antifungal medication), or methotrexate. There are exceptions. Taking a class of drugs called a CYP450 inducer (such as rifampin, a medication used to treat tuberculosis) at the same time as Otezla may reduce Otezla’s impact.

What about treatments in clinical trials?

Thanks to diligent scientific research, today’s treatments are providing a wide range of safe and effective options for people with psoriasis and/or psoriatic arthritis. And the search continues to find safer and even more effective treatments.

The National Psoriasis Foundation (NPF) tracks the movement of drugs for psoriasis and psoriatic arthritis from preliminary studies through the three phases of clinical trials as required by the U.S. Food and Drug Administration. This information is compiled, along with that from other sources, and entered into our drug research pipeline.

To learn more about research and upcoming treatments visit www.psoriasis.org/drug-pipline.
**BILL OF RIGHTS AND RESPONSIBILITIES**

For People with Psoriasis and Psoriatic Arthritis

01. You have the right to receive medical care from a health care provider who understands that psoriasis and psoriatic arthritis are serious autoimmune diseases that require lifelong treatment.

02. It’s your responsibility to get involved in managing your disease by participating in health care decisions, following treatment plans and making healthy lifestyle choices.

03. You have the right to a health care provider who can fully assess your disease and related conditions, knows the benefits and risks of treatments and medications, and readily coordinates treatment plans with your other providers.

04. It’s your responsibility to be honest with your health care provider about any health and lifestyle decisions that may affect the success of your treatment plan.

05. You have the right to clear or almost clear skin with effective treatment throughout your lifetime. Seek another health care provider if your current provider is not comfortable prescribing and monitoring psoriatic disease treatments.

06. It’s your responsibility to ask for support and encouragement from your loved ones, your doctors, and anyone else you feel comfortable with discussing personal and health issues.

07. You have the right to be treated in a courteous and nondiscriminatory manner by health care providers, employers and others.

**WE’RE HERE FOR YOU**

At NPF, our priority is giving you the information and services you need to take control of your psoriasis and/or psoriatic arthritis, while funding research to find a cure.

**Research**

Finding a cure for psoriasis and psoriatic arthritis is our highest priority. We’re working for you by:

- Funding promising new studies through our Discovery and Translational grants programs
- Increasing the number of scientists doing research through our Medical Dermatology Fellowship program
- Hosting the world’s largest collection of psoriasis DNA for genetic research

**Advocacy**

We’re ensuring that people with psoriasis and psoriatic arthritis have a say in the policies that affect their lives. Join us as we:

- Work to increase federal funding for psoriasis and psoriatic arthritis research
- Improve access to health care for patients
Health education

NPF is your one-stop shop for news and information about psoriasis and psoriatic arthritis. Visit www.psoriasis.org to learn more about:

- The latest treatment information and research updates
- Health events in your area

Connection

Sometimes the best resource to manage psoriasis and psoriatic arthritis is another person with your condition. Share information and get support from:

- TalkPsoriasis.org, the largest online community for people affected by psoriasis and psoriatic arthritis
- Psoriasis One to One mentor program: www.psoriasis.org/one-to-one
- Team NPF Walk, Run, Ride and DIY events: www.teamnpf.org

Learn more

Find more information and resources at www.psoriasis.org.

NPF is a 501 (c) (3) charitable organization governed by a volunteer Board of Directors and advised on medical issues by a volunteer Medical Board.

NPF’s educational materials are reviewed by members of our Medical Board and are not intended to replace the counsel of a physician.

NPF does not endorse any medications, products or treatments for psoriasis or psoriatic arthritis and advises you to consult a physician before initiating any treatment.

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Become a member of the National Psoriasis Foundation and get the tools and information you need to manage your psoriasis and/or psoriatic arthritis. As a member, you’ll receive a full year of *Psoriasis Advance* magazine and other benefits and services designed to help you live well with psoriatic disease.

- Yes, I want to join the National Psoriasis Foundation. Please send me a bill for $35. For faster service, join online at www.psoriasis.org or call 800-723-9166.

Name _______________________________

Address ______________________________

City __________________________________

State ________________ ZIP _____________

Phone _______________________________

Email address (to receive Foundation updates)

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