PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

COPELLOR, 80 mg/ml, solution for injection

Ixekizumab

Contains sugar

Read all of this leaflet carefully before you start using COPELLOR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- COPELLOR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What COPELLOR is and what it is used for
2. What you need to know before you use COPELLOR
3. How to use COPELLOR
4. Possible side effects
5. How to store COPELLOR
6. Contents of the pack and other information

1. What COPELLOR is and what it is used for

COPELLOR is a medicine that contains the active substance ixekizumab.

COPELLOR is intended for the treatment of the inflammatory diseases described below:

- Plaque psoriasis in adults
- Plaque psoriasis in children from the age of 6 and with a body weight of more than 50 kg
- Psoriatic arthritis in adults
- Radiographic Axial Spondyloarthritis in adults
- Non-radiographic Axial Spondyloarthritis in adults

Ixekizumab belongs to a group of medicines called interleukin (IL) inhibitors. This medicine works by blocking the activity of a protein called IL-17A, which promotes psoriasis and inflammatory disease of the joints and the spine.

Plaque psoriasis

COPELLOR is used to treat a skin condition called “plaque psoriasis” in adults and in children from the age of 6 years and with a body weight of more than 50 kg with moderate to severe disease. COPELLOR reduces the signs and symptoms of the disease. Using COPELLOR will benefit you by improvements of skin clearance and reducing your symptoms such as scaling, itching and pain.

Psoriatic arthritis

COPELLOR is used to treat a condition called “psoriatic arthritis” in adults, an inflammatory disease of the joints, often accompanied by psoriasis. If you have psoriatic arthritis, you will first be given other medicines. If you do not respond well enough to these medicines or in case of intolerance, you will be given COPELLOR to

reduce the signs and symptoms of the disease. COPELLOR can be used alone or with another medicine named methotrexate. Using COPELLOR will benefit you by reducing the signs and symptoms of the disease, improving physical function (ability to do normal daily activities), and slowing down the damage to the joints.

Axial spondyloarthritis

COPELLOR is used to treat adults with an inflammatory disease primarily affecting the spine which causes inflammation of the spinal joints, called axial spondyloarthritis. If the condition is visible using X-rays, it is referred to as “radiographic axial spondyloarthritis”; if it occurs in patients with no visible signs on X-rays, it is referred to as “non-radiographic axial spondyloarthritis”. If you have axial spondyloarthritis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given COPELLOR to reduce the signs and symptoms of the disease, reduce inflammation and improve your physical function.

2. What you need to know before you use COPELLOR

Do not use COPELLOR:

- if you are hypersensitive (allergic) to ixekizumab or any of the other ingredients of COPELLOR (listed in section 6). If you think you may be allergic, ask your doctor for advice before using COPELLOR.
- if you have an infection which your doctor thinks is important (for example, active tuberculosis).

Do not have any vaccinations while on treatment with COPELLOR.

Warnings and precautions

Talk to your doctor or health care provider before using COPELLOR:

- if you currently have an infection or if you have long-term or repeated infections.
- if you have an inflammatory disease affecting the gut named Crohn's disease.
- if you have an inflammation of the large intestine named ulcerative colitis.
- if you are receiving any other treatment for psoriasis (such as immunosuppressant or phototherapy with ultraviolet light) or for psoriatic arthritis.

COPELLOR is a medicine that affects the immune system and may lower the ability of the immune system to fight infections. COPELLOR may increase the risk of infections, which can sometimes be serious.

Your doctor should check for tuberculosis (TB) before beginning treatment with COPELLOR and may treat you for TB if there is a history of TB or if you have TB currently.

Your doctor should watch closely for signs and symptoms of TB during and after treatment with COPELLOR

If you are not sure if any of the above applies to you, talk to your doctor or nurse before using COPELLOR.

Inflammatory bowel disease (Crohn's disease or ulcerative colitis)

Stop using COPELLOR and tell your doctor or seek medical help immediately if you notice abdominal cramps and pain, diarrhoea, weight loss or blood in the stool (any signs of bowel problems). If you are not sure if any of the above applies to you, talk to your doctor or nurse before using COPELLOR.

Look out for infections and allergic reactions

COPELLOR can potentially cause serious side effects, including infections and allergic reactions. You must look out for signs of these conditions while you are using COPELLOR.

Stop using COPELLOR and tell your doctor or seek medical help immediately if you notice any signs of a serious infection or an allergic reaction. See signs listed in section 4.

Children and adolescents

Do not use this medicine for the treatment of plaque psoriasis in children under 6 years of age because it has not been studied in this age group. Do not use this medicine for the treatment of psoriatic arthritis in children and adolescents under 18 years of age because it has not been studied in this age group.

Other medicines and COPELLOR

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

If you have recently had or are due to have a vaccination. You should not be given certain types of vaccines while using COPELLOR**.**

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using COPELLOR.

Pregnancy

It is preferable to avoid the use of COPELLOR in pregnancy. The effects of this medicine in pregnant women are not known. If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using COPELLOR and for at least 10 weeks after the last COPELLOR dose.

Breastfeeding

Talk to your doctor if you would like to breastfeed or are breastfeeding, before taking COPELLOR. Women on COPELLOR should not breastfeed their babies.

Driving and using machines

You should not drive, use machinery, or perform any tasks that require concentration until you are certain that COPELLOR does not adversely affect your ability to do so safely.

COPELLOR contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 80 mg dose, that is to say essentially “sodium-free”.

COPELLOR also contains the following ingredients:

- sucrose
- polysorbate 80
- water for injection

Do not use COPELLOR if you are hypersensitive (allergic) to any of these.

3. How to use COPELLOR

Do not share medicines prescribed for you with any other person.

Always take COPELLOR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Each syringe and pen contains one dose of COPELLOR (80 mg). Each syringe and pen delivers one dose only.

COPELLOR is given by injection under your skin (subcutaneous injection). You and your doctor or nurse should decide if you should inject COPELLOR yourself.

It is important not to try to inject yourself until you have been trained by your doctor or nurse. A caregiver may also give you your COPELLOR injection after proper training.

The syringe must not be shaken. Read the “Instructions for Use” for the syringe carefully before using COPELLOR.

How much COPELLOR is given and for how long

Your doctor will decide how much COPELLOR you need and for how long.

The usual dose is stipulated below:

Plaque psoriasis in adults

- The first dose is 160 mg (two 80 mg injections) by subcutaneous injection. This may be given by your doctor or nurse.
- After the first dose, you will use an 80 mg dose (one injection) at Weeks 2, 4, 6, 8, 10, and 12. From week 12, you will use an 80 mg dose (one injection**)** every 4 weeks.

Plaque psoriasis in children (age 6 years and above with a body weight of > 50 kg)

The recommended dose given by subcutaneous injection in children with a body weight > 50 kg is 160 mg (two 80 mg injections) at Week 0, then 80 mg every 4 weeks.

Psoriatic arthritis

For psoriatic arthritis patients who also have moderate to severe plaque psoriasis:

- The first dose is 160 mg (two 80 mg injections) by subcutaneous injection. This may be given by your doctor or nurse.
- After the first dose, you will use an 80 mg dose (1 syringe) at weeks 2, 4, 6, 8, 10, and 12. From week 12, you will use an 80 mg dose (1 syringe) every 4 weeks.

For other psoriatic arthritis patients

- The first dose is 160 mg (two 80 mg injections) by subcutaneous injection. This may be given by your doctor or nurse.
- After the first dose you will use an 80 mg dose (1 syringe) every 4 weeks.

Axial spondyloarthritis

The recommended dose is 160 mg (two 80 mg injections) by subcutaneous injection at week 0, followed by 80 mg (1 syringe) every 4 weeks.

COPELLOR is for long term treatment. Your doctor, pharmacist or nurse will regularly monitor your condition to check that the treatment is having the desired effect.

If you use more COPELLOR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take COPELLOR

If you have forgotten to inject a dose of COPELLOR, inject the next dose as soon as you remember. Then talk to your doctor to discuss when you should inject the next dose.

Do not take a double dose to make up for forgotten individual doses. Speak to your doctor to discuss when you should inject the next dose.

If you stop taking COPELLOR

You should not stop using COPELLOR without speaking to your doctor first. If you stop treatment, symptoms of psoriasis or psoriatic arthritis may come back.

If you have any further questions on the use of COPELLOR, ask your doctor or pharmacist.

4. Possible side effects

COPELLOR can have side effects.

Not all side effects reported for COPELLOR are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking COPELLOR, please consult your doctor, pharmacist, or other health care professional for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Possible serious infection – the signs include:

- Fever, flu-like symptoms, night sweats.
- Feeling tired or short of breath, cough which will not go away.
- Warm, red and painful skin, or a painful rash with blisters
- Blisters or erosions that ooze or become crusty.

Serious allergic reaction – the signs may include:

- Difficulty breathing or swallowing.
- Low blood pressure, which can cause dizziness or light-headedness.
- Swelling of the face, lips, tongue or throat.
- Severe itching of the skin, with a red rash or raised bumps.

These are all very serious side effects. If you have them, you may have had a serious reaction to COPELLOR. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Very frequent side effects:

- Upper respiratory tract infections with symptoms such as sore throat and stuffy nose (nasopharyngitis).
- Injection site reactions (e.g. red skin, pain).

Frequent side effects:

- Nausea (feel the need to vomit).
- Tinea (fungal) infections such as athlete’s foot.

- Pain in the back of the throat.
- Cold sores of mouth, skin and mucous membranes (herpes simplex, mucocutaneous).

Less frequent side effects:

- Oral thrush (oral candidiasis).
- Influenza.
- Runny nose.
- Bacterial skin infection.
- Hives.
- Discharge from the eye with itching, redness and swelling (conjunctivitis).
- Signs of low levels of white blood cells, such as fever, sore throat or mouth ulcers due to infections (neutropenia).
- Low blood platelet count (thrombocytopenia).
- Eczema.
- Painful, itchy and fluid filled blisters (dyshidrotic eczema).
- Rash.
- Rapid swelling of the tissues of the neck, face, mouth or throat (angioedema)
- Abdominal cramps and pain, diarrhoea, weight loss or blood in the stool (signs of bowel problems).

Rare:

- Fungal infection of the oesophagus (oesophageal candidiasis)
- Redness and peeling of skin (exfoliative dermatitis).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Alternatively, suspected side effects can be reported to the holder of the certificate of registration at ade_za@lilly.com.

By reporting side effects, you can help provide more information on the safety of COPELLOR.

5. How to store COPELLOR

Store all medicines out of reach of children.

Store in a refrigerator between 2 °C - 8 °C.

Do not freeze.

Do not shake.

Protect from light.

Keep in original outer carton until required for use.

Patient-use storage:

COPELLOR may be stored unrefrigerated for up to 5 days at a temperature not above 30 °C.

Do not use COPELLOR after the expiry date which is stated on the syringe label and on the outer carton after “EXP”.

The expiry date refers to the last day of that month.

Do not use COPELLOR if you notice that the auto-injector/prefilled syringe is damaged, or the medicine is cloudy, distinctly brown, or has particles in it.

Return all unused medicine to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains or sewerage systems.

COPELLOR is for single use only.

6. Contents of the pack and other information

What COPELLOR contains

The active substance is ixekizumab.

Each auto-injector/prefilled syringe contains 80 mg of ixekizumab in 1 ml solution.

The other ingredients are sucrose; polysorbate 80; sodium hydroxide; water for injections.

What COPELLOR looks like and contents of the pack

COPELLOR is a solution in a clear glass syringe.

The colour of the solution may vary from colourless to slightly yellow to slightly brown.

Pack sizes of 1, 2, 3 prefilled syringes or auto-injectors.

Not all pack sizes may be marketed.

Holder of the certificate of registration

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