

Package leaflet: Information for the patient

Deprim 400 mg/80 mg tablets

Sulfamethoxazole/Trimethoprim

Please read all of this leaflet carefully before you start taking the medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any questions ask your doctor or your pharmacist.
- This medicine was prescribed for you only. Do not pass it on to others. It may harm them, even when their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Deprim is and what it is used for

Deprim 400 mg/80 mg tablets are made up of two different medicines called sulfamethoxazole and trimethoprim. Both belong to a group of medicines called antibiotics. They are used to treat infections caused by bacteria. Like all antibiotics, Deprim only works against some types of bacteria. This means that it is only suitable for treating some types of infections.

Deprim can be used to treat or prevent:

- lung infections (pneumonia or PCP) caused by a bacteria called *Pneumocystis jiroveci* (previously known as *Pneumocystis carinii*)
- infections caused by a bacteria called Toxoplasma (toxoplasmosis).

Deprim can be used to treat:

- bladder or urinary tract infections (water infections)
- lung infections such as bronchitis
- ear infections such as otitis media
- an infection called nocardiosis, it can affect the lungs, skin and brain.

2. What you need to know before you take Deprim

Do not take Deprim if:

- you are allergic (hypersensitive) to sulfamethoxazole, trimethoprim or any of the other ingredients of Deprim (listed in section 6).
- you are allergic to sulfonamide medicines. Examples include sulfonylureas (such as gliclazide and glibenclamide) or thiazide diuretics (such as bendroflumethiazide – a water tablet).
- you have liver or kidney problems.
- you have ever had a problem with your blood.
- it is for your child and they are less than 6 weeks old or were premature. Unless it is for the treatment or prevention of PCP. In this case, babies should be at least 4 weeks old.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Deprim.

Warnings and precautions

Before you take Deprim, tell your doctor or pharmacist:

- if you have severe allergies or asthma
- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Deprim appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.
- additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).
- these potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.
- the highest risk for occurrence of serious skin reactions is within the first weeks of treatment.
- if you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Deprim you must not be re-started on Deprim at any time.
- if you develop a rash or these skin symptoms, stop taking Deprim, seek urgent advice from a doctor and tell him that you are taking this medicine.
- if you have been told that you have a rare blood problem called porphyria, which can affect your skin or nervous system
- if you don't have enough folic acid (a vitamin) in your body - which can make your skin pale and make you feel tired, weak and breathless. This is known as anaemia
- if you have ever had jaundice which can cause yellowing of your skin or the whites of your eyes
- if you have a problem with your metabolism called phenylketonuria and are not on a special diet to help your condition
- if you are elderly
- if you are underweight or malnourished
- if you have been told by your doctor that you have a lot of potassium in your blood.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Deprim.

Other medicines and Deprim

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Deprim can affect the way some medicines work. Also some other

medicines can affect the way Deprim works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Diuretics (water tablets), which help increase the amount of urine you produce
- Pyrimethamine, used to treat and prevent malaria, and to treat diarrhoea
- Ciclosporin, used after transplant operations or for your immune system
- Medicines used to thin the blood such as warfarin
- Phenytoin, used to treat epilepsy (fits)
- Medicines for diabetes, such as glibenclamide, glipizide or tolbutamide (sulfonylureas)
- Medicines to treat problems with the way your heart beats such as digoxin or procainamide
- Amantadine, used to treat Parkinson's disease, multiple sclerosis, flu or shingles
- Medicines to treat HIV (Human Immunodeficiency Virus), called zidovudine or lamivudine
- Medicines that can increase the amount of potassium in your blood, such as diuretics (water tablets, which help increase the amount of urine you produce), steroids (like prednisolone) and digoxin
- Methotrexate, a medicine used to treat cancer or for your immune system.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Deprim.

Deprim with food and drink

You should take Deprim with some food or drink. This will stop you feeling sick (nausea) or having diarrhoea. Although it is better to take it with food, you can still take it on an empty stomach.

Drink plenty of fluid such as water while you are taking Deprim.

Pregnancy and breastfeeding

If you are pregnant, or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

3. How to take Deprim

Always take Deprim exactly as your doctor has told you. The label on your pack will tell you how much to take and how often to take it. You should check with your doctor or pharmacist if you are not sure.

Usual dose

Adults and children over 12 years:	The usual dose is two tablets in a morning and two tablets in an evening.
------------------------------------	---

For children below the age of 12 years, Trimethoprim & Sulfamethoxazole oral suspension is recommended.

The tablet can be divided into equal doses.

- Deprim should be taken for at least five days.
- Make sure that you finish the course of Deprim which your doctor has prescribed.

Special Dose

The dose of Deprim and how long you need to take it depends on the infection you have and how bad it is. Your doctor may prescribe you a different dose or length of course of Deprim to:

- treat urinary tract (water) infections
- treat and prevent lung infections caused by the bacteria *Pneumocystis jiroveci*
- treat infections caused by the bacteria *Toxoplasma* (toxoplasmosis) or *Nocardia* (nocardiosis).

If you have kidney problems your doctor may:

- prescribe a lower dose of Deprim
- take blood to test whether the medicine is working properly.

If you take Deprim for a long time your doctor may:

- take blood to test whether the medicine is working properly
- prescribe folic acid (a vitamin) for you to take at the same time as Deprim.

If you take more Deprim than you should

If you take more Deprim than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you.

If you have taken too much Deprim you may

- feel or be sick
- feel dizzy or confused.

If you forget to take Deprim

- If you forget to take a dose, take it as soon as you remember it.
- Do not take a double dose to make up for the forgotten dose.

4. Possible side effects

Like all medicines, Deprim can cause side effects, although not everybody gets them. You may experience the following side effects with this medicine. Stop taking Deprim and tell your doctor immediately if you have an allergic reaction.

Chances of an allergic reaction is very rare (fewer than 1 in 10,000 people are affected), signs of an allergic reaction include:

Allergic reactions

- Difficulty in breathing
- Fainting
- Swelling of face
- Swelling of mouth, tongue or throat which may be red and painful and/or cause difficulty in swallowing
- Chest pain
- Red patches on the skin

Very Common (more than 1 in 10 people)

- High levels of potassium in your blood, which can cause abnormal heart beats (palpitations).

Common (less than 1 in 10 people)

- An infection called thrush or candidiasis which can affect your mouth or vagina. It is caused by a fungus
- Headache
- Feeling sick (nausea)
- Diarrhoea
- Skin rashes

Uncommon (less than 1 in 100)

- Being sick (vomiting)

Very Rare (less than 1 in 10,000 people)

- Fever (high temperature) or frequent infections
- Sudden wheeziness or difficulty breathing
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see warnings and precautions)
- Mouth ulcers, cold sores and ulcers or soreness of your tongue
- Skin lumps or hives (raised, red or white, itchy patches of skin)
- Blisters on your skin or inside your mouth, nose, vagina or bottom
- Inflammation of the eye which causes pain and redness
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day)
- Low levels of sodium in your blood
- Changes in blood tests
- Feeling weak, tired or listless, pale skin (anaemia)
- Heart problems
- Jaundice (the skin and the whites of your eyes turn yellow). This can occur at the same time as unexpected bleeding or bruising
- Pains in your stomach, which can occur with blood in your faeces (poo)
- Pains in your chest, muscles or joints and muscle weakness
- Arthritis
- Problems with your urine. Difficulty passing urine. Passing more or less urine than usual. Blood or cloudiness in your urine
- Kidney problems
- Sudden headache or stiffness of your neck, accompanied by fever (high temperature)
- Problems controlling your movements
- Fits (convulsions or seizures)
- Feeling unsteady or giddy
- Ringing or other unusual sounds in your ears
- Tingling or numbness in your hands and feet
- Seeing strange or unusual sights (hallucinations)
- Depression
- Muscle pain and/or muscle weakness in HIV patients.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Deprim

Keep this medicine out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

Stored below 25 °C. Protect from light and moisture.

6. Contents of the pack and other information

What Deprim contains

- The active substances are sulfamethoxazole and trimethoprim. Each tablet contains 400 mg sulfamethoxazole and 80 mg trimethoprim.
- The other ingredients are microcrystalline cellulose, povidone, glycerol, sodium starch glycolate, magnesium stearate and talc.

What Deprim looks like and contents of the pack

White to off-white, round, flat, scored tablets.

Pack sizes

PVC/Aluminium blisters. Pack-size of 20 tablets.

Marketing Authorisation Holder and Manufacturer

Remedica Ltd

Aharnon Str., Limassol Industrial Estate

3056 Limassol, Cyprus

This leaflet was last revised in 02/2018.

For internal use only: am-pl-deprim-480mg-tabs-a0