



For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory

ONCE-DAILY

Meslataj[®] DR

(mesalamine)
Delayed Release Tablets USP

Meslataj-DR prolonged Release Tablets 1.2gm (Mesalamine)

Patient Information

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

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1. WHAT Meslataj-DR IS AND WHAT IT IS USED FOR

The name of this medicine is Meslataj-DR prolonged Release Tablets. Each tablet contains Mesalamine 1.2gm as the active ingredient. Mesalamine belongs to a group of medicines called salicylates. Meslataj-DR is used to treat mild to moderate inflammation of the gut caused by a condition called ulcerative colitis. It can also be used to control the condition and prevent it from coming back. The tablets release the active ingredient slowly which then acts locally to reduce the inflammation and help relieve or stop the pain.

2. BEFORE YOU TAKE Meslataj-DR

- Do Not take Meslataj-DR if you :
 - are allergic to Mesalamine or any of the other ingredients in Meslataj-DR (see section 6)
 - are allergic to any other salicylates e.g. aspirin
 - have severe liver or kidney problems
- Take special care with Meslataj-DR You should consult your doctor before taking these tablets if:
 - you experience any unexplained bleeding, bruising, skin rashes, fever or sore throat while

using this medicine, stop using this medicine and seek medical advice as soon as possible.

- You experience any chest pain, an increased heartbeat and excess tiredness while using this medicine, stop using this medicine and seek medical advice as soon as possible.
- You suddenly develop abdominal cramps, abdominal pain, fever, severe headache and rash, stop using this medicine and seek medical advice immediately.
- you have lung problems, in particular asthma.
- you currently have, or have previously had liver or kidney disease
- you are on any medication that may affect kidney function e.g. azathioprine
- you have ever had an allergy to a medication called sulphasalazine
- If you suffer from kidney problems you will require regular check ups by your doctor.
- You should make sure that you don't become dehydrated, while you are taking this medicine. This can occur after severe or prolonged attacks of vomiting and/or diarrhoea, high fever or heavy sweating. If this does occur, you should speak to a doctor or pharmacist for advice as soon as possible.

Taking with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

This is especially important if you are taking any of the following :

- Azathioprine, 6-mercaptopurine or thioguanine
 - Certain agents that inhibit blood clotting (medicines for thrombosis or to thin your blood, e.g. warfarin) Pregnancy and Breastfeeding
- If you are pregnant, are planning to become pregnant or are breastfeeding you should speak to your doctor or pharmacist for advice before taking this medicine.
- There is limited experience with the use of Mesalamine during pregnancy and breast-feeding. The newborn may develop allergic reactions after breast-feeding, e.g. diarrhoea. If the newborn develops diarrhoea, breast-feeding should be discontinued.

3. HOW TO TAKE Meslataj-DR

Always take Meslataj-DR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The tablets should be taken by mouth either whole or broken up, they should not be crushed or chewed. If you have difficulty swallowing the tablets you can disperse them in a small quantity of cold water (approximately 50ml) then stir and drink immediately. Adults To treat an attack of colitis, your doctor will usually prescribe a dose of up to 4g mesalamine, to be taken as eight tablets once a day or in two or three

divided doses.

To help prevent further attacks, your doctor will usually prescribe a dose of 2g Mesalamine, to be taken as four 1.2gm tablets once a day. Children 6 years of age and older: The dose for children will be calculated by your doctor and depends on the child's weight. It is generally recommended that half the adult dose is given to children up to 40 kg of body weight and the normal adult dose to children above 40 kg of body weight.

If you take more Meslataj-DR than you should If you accidentally take too many tablets, you should go to your nearest emergency department or contact your doctor immediately. Take the pack and any remaining tablets with you.

If you forget to take Meslataj-DR

If you forget to take a dose, take the next dose as soon as you remember, unless it is less than 3 hours until your next dose.

Do not take a double dose to make up for the forgotten one. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Meslataj-DR can cause side effects, although not everyone gets them.

STOP taking Meslataj-DR if you notice:

- itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing or wheeziness (signs of an allergic reaction).
- unexplained bleeding, bruising, skin rashes, fever or sore throat (signs of a blood disorder).
- a change in the colour or amount of urine produced (signs of kidney problems).
- If you experience any of the above side effects you should contact your doctor or go to the nearest hospital emergency department immediately.

Other side effects include:

- Rare side effects (affecting less than 1 in 1,000 patients) include:
 - vomiting
 - stomach pain
 - nausea
 - diarrhoea
 - headache
 - inflammation of the heart or area surrounding the heart
 - Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).
- Very rare side effects (affecting less than 1 in 10,000 patients) include:
 - raised liver enzymes
 - hair loss (reversible)
 - joint and muscle pain
 - allergic reactions and fever
 - lupus erythematosus (an auto-immune disorder affecting the skin)

- semen with a low concentration of sperm (oligospermia) (this is reversible)
 - blood disorders (e.g. low levels of red blood cells)
 - tingling or numbness in the hands and feet
 - allergic and fibrotic lung reactions (including breathing problems)
 - changes in kidney function or kidney failure
 - inflammation of the pancreas
- Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist.
This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE Meslataj-DR

Do not store above 25°C.
Store in original packaging and do not use after the expiry date detailed on the pack.
Keep out of sight and reach of children.

6. FURTHER INFORMATION

What Meslataj-DR contains
Each tablet contains 1.2gm of the active ingredient, Mesalamine.
What Meslataj looks like and the contents of the pack
Each film coated prolonged release tablet contains. Mesalamine USP 1.2gm
Excipients Q.S.
Colour: Red Oxide of Iron
Each carton contains 30,50 & 100 tablets presented in blister strips of 10 tablets per strip.



Manufactured in India by:
TAJ PHARMACEUTICALS LTD.
15-6-108 Afzal Gunj,Hyderabad TS 400 012, India.
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DISCLAIMER: THE INFORMATION GIVEN BELOW IS FOR THE USE OF MEDICAL SALES REP AND IS NOT FOR DOCTORS.
This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.
This leaflet was last revised in Feb 2019.
Not all pack sizes may be marketed.

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