Package leaflet: Information for the user

Octasa 800 mg Modified Release Tablets
mesalazine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if 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 Octasa is and what it is used for

Octasa contains the active substance mesalazine. This is an anti-inflammatory medicine used to treat ulcerative colitis and Crohn's ileo-colitis.

Octasa is used:
- to treat and prevent further episodes of ulcerative colitis
- to prevent further episodes of Crohn's ileo-colitis once the disease has been brought under control.

Ulcerative colitis is a disease of the large bowel (colon) or back passage (rectum), in which the lining of the bowel becomes inflamed (red and swollen).

Crohn's ileo-colitis is a disease that affects the small bowel (terminal ileum) and the large bowel (colon) in which the lining of the bowel becomes inflamed. This can lead to ulcers, abscesses and narrowing (strictures) in the bowel.

Octasa acts locally at the site of inflammation (colon, rectum and terminal ileum) to reduce this inflammation.

2. What you need to know before you take Octasa

Do not take Octasa
- If you are allergic to mesalazine or any of the other ingredients of this medication (listed in section 6)

- If you are allergic to salicylates (e. g. aspirin)
- If you have severe kidney problems
- If you have severe liver problems

Warnings and precautions
Talk to your doctor before taking Octasa if you have any medical conditions or illnesses, particularly if you have:
- ever had any problems with your kidneys. This is especially important if you are elderly.
- any lung problems, e. g. asthma.
- suffered an allergy to sulfasalazine in the past.
- ever had allergic reactions of your heart such as inflammation of the heart muscle or heart sac. If you have had previous suspected mesalazine-induced allergic reactions of your heart, then Octasa must not be taken. Octasa can be taken with care if you have had a previous allergic reaction of the heart not caused by mesalazine.
- If you have an ulcer of the stomach or intestine, you may take Octasa with care
- ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears contact your doctor immediately.

Serious skin reactions including Drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) have been reported in association with mesalazine treatment. Stop using mesalazine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

If you have an ulcer of the stomach or intestine, you may take Octasa with care.

Kidney stones may develop with use of Octasa. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with Octasa.

Mesalazine may produce red-brown urine discoloration after contact with sodium hypochlorite bleach in the toilet water. It concerns a chemical reaction between mesalazine and bleach and is harmless.

Test for your liver, kidney and blood
Before and while you are taking Octasa, your doctor may want to monitor you from time to time, to check that your liver, kidneys, blood and lungs are all right.
There have been a few reports of intact tablets in the stool. What appear to be intact tablets may sometimes be the remains of the tablet coating. If you often observe tablets or tablet shells in the stool, you should consult your doctor.

Children and adolescents
Octasa is only recommended for use in children 6 years and older.

Other medicines and Octasa
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines such as:

- drugs affecting the immune system (e. g. azathioprine, or 6-mercaptopurine or thioguanine)
- drugs that prevent the formation of blood clots (anticoagulants, e.g., warfarin)

Octasa with food, drink and alcohol
You may eat and drink normally (including alcohol), when taking Octasa.

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

Driving and using machines
Octasa is not expected to affect your ability to drive or operate machinery. However, if you are affected in anyway do not drive or operate machinery.

Important information about some of the ingredients of Octasa
People who are intolerant to **lactose** should note that Octasa contains a small amount of lactose. If you doctor has told you that you have intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, i.e. is essentially "sodium-free".

3. How to take Octasa

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Octasa should be taken before meals. This medication must be swallowed whole preferably with some liquid. Do not chew, crush or break the tablets before swallowing them.

Whilst taking this medication ensure you drink adequate fluids to remain well hydrated, especially after severe or prolonged episodes of vomiting and/or diarrhoea, high fever or heavy sweating. This is to avoid problems with your kidney.

The recommended dose is:

Adults (including the elderly)
To treat acute phases of ulcerative colitis your daily dose is 3 to 6 tablets.
3 tablets may be taken once daily or in divided doses (as advised by your doctor).
Above 3 tablets a day should be taken in divided doses.

To prevent ulcerative colitis or Crohn's ileo-colitis your daily dose is 2 to 3 tablets once daily or in divided doses. Do not take more than 6 tablets per day, and do not take more than 3 tablets together at the same time.

Use in children and adolescents
Octasa is only recommended for use in children 6 years and older.
The daily dose depends on the child's weight.

- *To treat acute phases of ulcerative colitis*:

20-30 kg weight: one tablet per day.
30-40 kg weight: one to two tablets per day in divided doses.
Above 40 kg weight: two to three tablets per day in divided doses.
The total dose should not exceed 4 g/day.

- *To prevent ulcerative colitis or Crohn's ileo-colitis*:

30-40 kg weight: one tablet per day.
Above 40 kg weight: one to two tablets per day in divided doses.
The total dose should not exceed 2 g/day.

It is generally recommended that half the adult dose may be given to children up to 40 kg weight; and the normal adult dose to those above 40 kg.

If you take more Octasa than you should
You should not take a higher dose than your doctor has prescribed for you. Contact your nearest hospital casualty department or a doctor for advice if you or anyone else has swallowed too many tablets or if you think a child has swallowed any. Take this leaflet, and any tablets that you still have to show the doctor.

If you forget to take Octasa
If you forget to take a dose at the right time, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Octasa
Do not stop taking Octasa without talking to your doctor first even if you feel better.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side-effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Organ specific side effects affecting the heart, lungs, liver, kidneys, pancreas, skin and subcutaneous tissue have been reported.

Stop taking the medicine and seek urgent medical advice immediately if you experience any of the following:

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, widespread rash, fever and enlarged lymph nodes. These serious skin rashes can be preceded by fever and flu-like symptoms
- Unexplained bruising (without injury), bleeding under your skin, purple spots or patches under your skin, anaemia (feeling tired, weak and looking pale, especially on lips, nails and inside of eyelids), fever (high temperature), sore throat or unusual bleeding (e.g. nose bleeds).
- Lung disease (scarring of lung tissue, allergic reaction) resulting in difficulty in breathing, cough, wheezing and collection of fluid in the lungs, pneumonia
- Abnormal liver function tests, hepatitis (inflammation of the liver giving rise to flu-like symptoms and jaundice)

- Inflammation of the heart with signs like chest pains or palpitations
- Disorder of the immune system (lupus-like syndrome) which can cause inflammation of the heart sac or membranes around the lungs and heart, rash and /or joint pain
- Kidney problems (associated with blood in urine and/or swelling in feet and ankles), kidney failure, which may be reversible if treatment is stopped early

Tell your doctor immediately if you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears. These could be symptoms of increased pressure within your skull (idiopathic intracranial hypertension) (frequency not known [cannot be estimated from the available data]).

The following side effects have been reported at the approximate frequencies shown:

Common (may affect up to 1 in 10 people)
- rash
- indigestion

Uncommon (may affect up to 1 in 100 people)
- fever
- high number of white blood cells called eosinophil granulocytes
- sensation of tingling, pricking and numbness
- hives, itching skin
- chest pain

Rare (may affect up to 1 in 1000 people)
- headache
- dizziness
- diarrhoea, stomach pain, wind (flatulence), feeling of unease and discomfort in the stomach with an urge to vomit and vomiting
- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

Very rare (may affect up to 1 in 10000 people)
- severe reduction in blood cells which can cause weakness, bruising or make infections more likely, low blood cell counts; reduction in blood platelets which increases the risk of bleeding
- allergic reactions such as rash or skin eruption
- fever that occurs while taking the medicine and which disappears when the medicine is stopped (drug fever)
- immune system disease that can involve organs and joints
- ulcerative colitis involving the entire large intestine
- abnormal or damaged nerves giving a sensation of numbness or tingling
- inflamed pancreas (associated with pain in upper abdomen and back and feeling sick)
- abnormal liver function tests, hepatitis (inflammation of the liver giving rise to flu-like symptoms and jaundice)
- muscle or joint pain
- hair loss
- reversible decrease in sperm production

Not known (frequency cannot be estimated from available data)
- inflammation of the membranes of the pleural cavity surrounding the lungs (pleurisy)
- intolerance to mesalazine sometimes with worsening symptoms of underlying disease
- kidney stones and associated kidney pain (see also section 2)
- weight loss
- laboratory test results out of normal range

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report any side effects directly via the Yellow Card Scheme online at yellowcard.mhra.gov.uk or via the free Yellow Card app.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Octasa

- Keep out of the sight and reach of children.
- Do not store above 25 °C.
- Keep the tablets in the original package to protect them from moisture.
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Do not use this medicine after the expiry date which is stated on the outer packaging.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

Is this leaflet hard to see or read? Telephone 0800 1985000 for help.

What Octasa contains
The active substance is mesalazine. Each tablet contains 800 mg mesalazine
The other ingredients are lactose monohydrate, sodium starch glycolate (Type A), triethyl citrate, talc E553b, methacrylic acide – methylmethacrylate copolymer (1:2), povidone E1201, magnesium stearate (vegetable origin), iron oxides E172, macrogol 6000

What Octasa looks like and contents of the pack
Octasa 800 mg Modified Release Tablets are red-brown, oblong, tablets.
They are available in pack sizes of 90 or 180 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is:

Tillotts Pharma UK Ltd,
Wellingore Hall, Wellingore
Lincolnshire, LN5 0HX, UK
Tel: + 44 (0) 1522 813500
e-mail: ukinfo@tillotts.com

The manufacturer is:

Haupt Pharma Wülfing GmbH,31028 Gronau,Germany
Rottendorf Pharma GmbH, 59320 Ennigerloh, Germany
Tillotts Pharma GmbH, 79618 Rheinfelden, Germany

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only)

Please be ready to give the following information:

Product name **Octasa 800 mg Modified Release Tablets**
Reference number: PL 36633/0001

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