

Package leaflet: Information for the user

Octasa 400 mg Modified Release Tablets
Active substance: mesalazine

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, please 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 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
2. What you need to know before you take Octasa
3. How to take Octasa
4. Possible side-effects
5. How to store Octasa
6. Contents of the pack and other information

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 liver or 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 mesalazine-induced allergic reactions of your heart, then do not take Octasa. Octasa can be taken with care if you have had a previous allergic reaction of the heart even if not caused by taking mesalazine.

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

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

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

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 medicine must be swallowed whole preferably with some liquid. Do not chew, crush or break the tablets before swallowing them.

Whilst taking this medicine 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 ulcerative colitis, your daily dose is 6 to 12 tablets. 6 tablets may be taken once daily or in divided doses (as advised by your doctor). Above 6 tablets a day should be taken in divided doses.

To prevent Crohn's ileo-colitis or ulcerative colitis your daily dose is 3 to 6 tablets once daily or in divided doses. Follow your doctor's instructions. Do not take more than 12 tablets a day and do not take more than 6 tablets 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: two to three tablets per day.

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

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

20-30 kg weight: one tablet per day.

30-40 kg weight: one to 2 tablets per day

40 kg weight: one to three 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 tablet, 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 Octasa and seek urgent medical advice immediately

If you develop 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)

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

Common:

- rash
- indigestion

Uncommon

- fever
- high number of white blood cells called eosinophil granulocytes
- sensation of tingling, pricking and numbness
- hives, itching skin
- chest pain

Rare

- headache
- dizziness
- inflammation of the heart with signs like chest pains or palpitations
- 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

- 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
- lung disease (scarring of lung tissue, allergic reaction) resulting in difficulty in breathing, cough, wheezing and collection of fluid in the lungs, pneumonia
- 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
- kidney problems (such as inflammation and scarring of the kidney), kidney failure, which may be reversible if treatment is stopped early

- reversible decrease in sperm production.

Not known

- 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
- inflammation of the membranes of the pleural cavity surrounding the lungs (pleurisy)
- intolerance to mesalazine sometimes with worsening symptoms of underlying disease
- weight loss
- laboratory test results out of normal range.

Evaluation of the side effects is based on the following frequencies:

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data

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 at yellowcard.mhra.gov.uk. 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 reach and sight of children.
- Do not store above 25 °C.
- Keep the tablets in the original package to protect them from moisture.

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 400 mg mesalazine

The other ingredients are: lactose monohydrate, sodium starch glycolate (Type A), triethyl citrate, E553b, methacrylic acid – 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 400 mg Modified Release Tablets are red-brown, oblong, tablets.

They are available in pack sizes of 90 or 120 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
United Kingdom Tel: + 44 (0) 1522 813500

The manufacturer is:

Haupt Pharma Wülfing GmbH, D – 31028 Gronau, Germany
Rottendorf Pharma GmbH, Ostenfelder Strasse 51 – 61, 59320 Ennigerloh, Germany

This information applies only to Tillotts Pharma UK Ltd. Octasa 400 mg Modified Release Tablets.
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