Package leaflet: Information for the user

Octasa 1600 mg Modified Release Tablets

Read all of this leaflet carefully before you start using 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, 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. It is an anti-inflammatory medicine used for the treatment of ulcerative colitis. Ulcerative colitis is a disease in which the lining of the large intestine (colon) or the back passage (rectum) becomes inflamed (red and swollen). This may lead to frequent and bloody stools, often with abdominal cramps.

Octasa treats and prevents inflammation throughout the entire colon and rectum (mild to moderate acute ulcerative colitis and for the prevention of relapse).

2. What you need to know before you use Octasa

Do not use Octasa:
- if you are allergic to mesalazine or any of the other ingredients of this medicine (listed in Section 6).
- if you are allergic to salicylates (e.g. acetylsalicylic acid)
- if you have severe liver problems
  if you have severe kidney problems

Warnings and precautions

Talk to your doctor or pharmacist before using Octasa if you have any medical conditions or illnesses, particularly if you have:
- any lung disease problems, e.g. asthma.
- impaired function of kidneys, liver or lungs, especially if you are elderly.
- suffered an allergy to sulphasalazine in the past.
  had an allergic reaction 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 used. Octasa can be used with care if you have had a previous allergic reaction of the heart not caused by mesalazine.
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

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 Octasa 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 a stomach ulcer, you should use Octasa with care.

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

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 check that your liver, kidneys, blood and lungs are working properly.

Children and adolescents
Do not give this medicine to children or adolescents under the age of 18 years of age, because Octasa has not been tested in this age group.

Other medicines and Octasa
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines such as:
- Medicines that prevent the formation of blood clots (anticoagulants, e.g. warfarin). The effect of these medicines could be increased or decreased, the effect this may have on you is unclear.
- Medicines affecting the immune system (e.g. azathioprine, 6-mercaptopurine or thioguanine). Used together with Octasa, these medicines may lead to life-threatening infections (see Section 4).
- Non-steroidal anti-inflammatory drugs (for example: medicines containing acetylsalicylic acid, ibuprofen or diclofenac)

Octasa with food and drink
Please refer to Section 3.

Pregnancy and breast-feeding
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. Since mesalazine is excreted in breast milk in small quantities, due care should be taken if using Octasa whilst breast-feeding. If the infant develops diarrhoea, breast-feeding should be discontinued.

Driving and using machines
Octasa has no or negligible influence on the ability to drive and use machines. However, if you are affected in any way you should not drive or operate machinery.

Octasa contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to use Octasa

Always use Octasa exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The tablets must be swallowed whole preferably with a glass of water. Do not chew, crush or break the tablets before swallowing. This is important for these tablets with modified release, if the tablets are not swallowed whole, they may not work as intended.

Octasa can be taken with or without food.

Your doctor will decide which dose you should take.

The recommended dose is:
Adults
Active phase of disease: When the disease is getting worse, the dose can be increased up to 4800 mg (three tablets) daily taken once daily *or* as one tablet 2 to 3 times a day.
Maintenance treatment: 1600 mg taken daily.

If you take more Octasa than you should
If you take more Octasa than you should, or if children have been taking medicine by accident, please contact your doctor, the nearest hospital or pharmacy to get an opinion of the risk and advice on action to be taken. Take the box with you, if possible

If you forget to take Octasa
If you forget to take a dose at the right time, just take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you stop using Octasa
Use Octasa for as long as your doctor prescribed it to you. Talk to your doctor before changing or stopping the treatment.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Octasa and seek medical attention immediately if you notice any of the following symptoms:

- 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 and nails), fever (high temperature), acute stomach pain, sore throat or unusual bleeding (e.g. nose bleeds).

Octasa can in very rare cases affect the white blood cells so, in those cases, your immune system could get worse. If you get an infection with symptoms such as fever with serious worsening of your general condition, or fever with local symptoms of infection such as sore throat/pharynx/mouth or urinary problems you should immediately see your doctor. Blood tests can then be taken to check for lack of white blood cells (agranulocytosis). It is important that you inform your doctor about all of your medications.

Other side effects:
Common: ***may affect up to 1 in 10 people***
- rash
- indigestion

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

Rare: ***may affect up to 1 in 1,000 people***
- 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: ***may affect up to 1 in 10,000 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
- 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 or 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)
- hair loss
- muscle or joint pain
- 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: ***frequency cannot be estimated from the available data***
- 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 mucosa surrounding the lungs and the thoracic cavity (pleurisy)
- Intolerance to mesalazine and / or exacerbation of 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 side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Octasa

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

Do not take this medicine after the expiry date which is stated on the carton and the blister strips.The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

No special requirements for disposal.

6. Contents of the pack and other information

What Octasa contains:
- The active substance is mesalazine. One tablet contains 1600 mg mesalazine.
- The other ingredients are:
  - magnesium stearateE 470B

- methacrylic acid-methyl methacrylate copolymer (1:2)
- triethylcitrate
- iron oxide yellow (E 172)
- iron oxide red (E 172)
- macrogol
- microcrystalline cellulose
- glycerol monostearate 40-55
- hypromellose
- maize starch
- polysorbate 80
- potassium dihydrogen phosphate
- colloidal anhydrous silica
- sodium starch glycolate (type A).

What Octasa looks like and contents of the pack
Octasa 1600 mg modified-release tablets are reddish brown in colour. The tablets are oblong shaped and approximately 2.3 cm in length, 1.1 cm in width and 0.9 cm in thickness.
Tablets are available in packs in blister strips. The blister strips are packed in a carton containing either 30 tablets, 60 tablets or 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
MA Holder:
Tillotts Pharma UK Limited
Wellingore Hall
Wellingore
Lincolnshire, LN5 0HX
United Kingdom

Manufacturer:
Haupt Pharma Wülfing GmbH
Bethelner Landstrasse 18
D - 31028 Gronau
Germany

Tillotts Pharma GmbH
Warmbacher Str. 80
DE - 79618 Rheinfelden
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Yaldigo 1600 mg Tablette mit veränderter Wirkstofffreisetzung
Belgium	Asamovon 1600 mg comprimés à libération modifiée
Czech Republic	Asacol
Denmark	Asacol
Estonia	Yaldigo
Germany	Asacol 1600 mg Tablette mit veränderter Wirkstofffreisetzung
Greece	Yaldigo
Finland	Asacol 1600 mg säädellysti vapauttavat tablettit
Ireland	Asacolon 1600 mg Modified-release tablet
Iceland	Asacol 1600 mg töflur með breyttan losunarhraða
Lithuania	Yaldigo 1600 mg modifikuoto atpalaidavimo tabletės
Latvia	Yaldigo 1600 mg modificētās darbības tabletes

Netherlands	Yaldigo 1600 mg, tabletten met gereguleerde afgifte
Norway	Asacol 1600 mg tabletter med modifisert frisetting
Sweden	Asacol 1600 mg tabletter med modifierad frisättning

This leaflet was last approved in July 2023