

## **Package leaflet: Information for the patient**

### **Destolit 150 mg tablets Ursodeoxycholic acid**

**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, 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 side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

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

#### **1. What Destolit is and what it is used for**

Destolit contains ursodeoxycholic acid, which is one of a group of medicines used to dissolve gallstones. Not all gallstones are suitable for treatment with Destolit but your doctor has decided that your condition may be treated this way. Ursodeoxycholic acid is a chemical present naturally in the body and it helps to control the amount of cholesterol in the blood. Destolit tablets help dissolve gallstones that are made mainly of cholesterol.

#### **2. What you need to know before you take Destolit**

##### **Do not take Destolit:**

- if you have acute inflammation of the gall bladder or biliary tract
- if you have a blockage of the biliary tract
- if you have frequent episodes of biliary colic (recurrent pain in the upper abdomen)
- if you have a stomach or duodenal ulcer
- if you have had bowel surgery (removal of a part of the small bowel)
- if you have inflammatory bowel disease
- if your gall bladder does not work properly
- if you have any liver disease
- if your doctor has told you that you have gallstones which are radio-opaque

- if you are allergic (hypersensitive) to ursodeoxycholic acid or any of the other ingredients of this medicine (listed in section 6).
- If you have a liver or intestinal condition which interferes with the circulation of bile substances e.g. blockage of the bile duct, removal of part of the small bowel.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Destolit.

### **Other medicines and Destolit**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. These may include:

- Hormone replacement therapy or the contraceptive pill.
- Colestyramine, colestipol and clofibrate (medicines which lower blood cholesterol).
- Antacids (which are medicines to relieve indigestion or heartburn).
- Ciclosporin (used to dampen down the body's immune reactions).
- Activated charcoal for indigestion, wind and heartburn.
- Ciprofloxacin and dapsone (antibacterials used to treat infections).
- Nitrendipine (used to treat high blood pressure).

### **Destolit with food and drink**

Destolit should be taken after meals, with one dose always being taken after the evening meal.

### **Pregnancy, breast-feeding and fertility**

#### **Pregnancy**

Destolit **should not** be taken during pregnancy unless recommended by your doctor.

#### **Breast-feeding**

**Do not** take Destolit whilst breast-feeding.

#### **Fertility**

Women should use adequate contraception during treatment with Destolit. Contraception should either be non-hormonal e.g. barrier methods or a low oestrogen contraceptive pill. Other oral contraceptive pills should not be taken with Destolit.

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**

Destolit should not affect your ability to drive or use machines.

## **3. How to take Destolit**

### **Adults and the elderly**

Always take Destolit exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- The usual dose is between 3 and 4 tablets a day. The dose is usually divided up and taken twice a day, i.e. 1 or 2 tablets taken with water after meals. One of the doses should always be taken after your evening meal.
- Destolit will work best if taken together with a low cholesterol and calorie controlled diet. You should discuss this with your doctor.
- You will not normally take Destolit for more than 2 years. Your doctor will give you regular check-ups.
- If you develop diarrhoea when taking Destolit please consult your doctor.

#### **Use in children and adolescents**

Destolit is not recommended in children and adolescents.

#### **If you take more Destolit than you should**

You should tell your doctor if you have taken more Destolit than you should. It is unlikely that you will notice any problems but you may experience diarrhoea.

#### **If you forget to take Destolit tablets**

- **Do not** worry, take them as soon as you remember. If it is nearly time for the next dose then take only that dose.
- **Do not** take a double dose to make up for a forgotten dose.

**If you stop taking Destolit tablets** even for a short amount of time, it may cause the gall stones to come back. **Do not** stop taking Destolit until you are advised by your doctor.

#### **This product contains lactose.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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.

Possible side effects include:

Common (**may affect up to 1 in 10 people**)

- Diarrhoea, pasty stools

Very Rare (may affect up to 1 in 10,000 people)

- A nettle like rash, gallstone calcification (a process in which the mineral calcium builds up in tissue causing it to harden).

Other side effects may include:

- Feeling or being sick and itchy skin

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

### **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 Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Destolit**

Keep all medicines out of the sight and reach of children.

**Do not** store above 25°C.

**Do not** use Destolit after the expiry date which is printed or embossed on the carton and blister as month/year. The expiry date refers to the last day of the month.

## **6. Contents of the pack and other information**

### **What Destolit contains**

The active substance is ursodeoxycholic acid. Each tablet contains 150 mg ursodeoxycholic acid.

The other ingredients are lactose, pregelatinised maize starch, acacia gum, talc, magnesium stearate and purified water.

### **What Destolit looks like and contents of the pack**

Each carton contains 6 blisters of 10 white tablets.

### **Marketing Authorisation Holder**

Norgine Pharmaceuticals Limited, Norgine House,  
Widewater Place. Moorhall Road  
Harefield, Uxbridge, UB9 6NS, UK

### **Manufacturer**

Norgine Ltd,  
Hengoed,  
Mid Glamorgan,  
CF82 8SJ,

UK

**If you need the information on this leaflet in an alternative format, such as large text, or Braille please ring from the UK: 0800 198 5000.**

The leaflet was last revised in June 2018