



**B. PACKAGE LEAFLET**



**Package Leaflet: Information for the user**

**TARGAXAN® 550 mg film-coated tablets**  
**rifaximin**

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

**What is in this leaflet:**

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

**1. What TARGAXAN is and what it is used for**

Targaxan contains the active substance rifaximin. Targaxan is an antibiotic that destroys bacteria, which can cause a disease called hepatic encephalopathy (symptoms include agitation, confusion, muscle problems, difficulty in speaking and in some cases coma).

Targaxan is used in adults with liver disease to reduce the recurrence of episodes of overt hepatic encephalopathy.

Targaxan can either be used alone or more commonly together with medicines containing lactulose (a laxative).

**2. What you need to know before you take TARGAXAN**

Do not take Targaxan:

- if you are allergic to:
  - rifaximin
  - similar types of antibiotics (such as rifampicin or rifabutin)
  - any of the other ingredients of this medicine (listed in section 6).
- if you have a blockage in your intestine



### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Targaxan.

While you are taking Targaxan your urine may turn a reddish colour. This is quite normal.

Treatment with any antibiotic including rifaximin may cause severe diarrhoea. This can happen several months after you have finished taking the medicine. If you have severe diarrhoea during or after using Targaxan you should stop taking Targaxan and contact your doctor immediately.

If your liver problems are severe your doctor will need to observe you carefully.

### **Targaxan contains sodium**

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

### **Children and adolescents**

Targaxan is not recommended for children and adolescents aged under 18 years. This medicine has not been studied in children and adolescents.

### **Other medicines and Targaxan**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Please tell your doctor if you are taking any of the following medicines:

- antibiotics (medicines to treat infections)
- warfarin (medicine to prevent blood clotting)
- antiepileptics (medicines for the treatment of epilepsy)
- antiarrhythmics (medicines to treat abnormal heart beat)
- ciclosporin (immunosuppressor)
- oral contraceptives

### **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 any medicine.

It is not known if Targaxan can harm your unborn baby. Targaxan is therefore not to be used if you are pregnant.

It is not known if rifaximin may be passed to your baby in breast milk. Targaxan is therefore not to be used if you are breast-feeding.

### **Driving and using machines**

Targaxan does not normally affect the ability to drive and use machines, but may cause dizziness in some patients. If you feel dizzy you should not drive or operate machinery.



### 3. How to take TARGAXAN

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

The recommended dose is 1 tablet twice a day taken with a glass of water.

Your doctor will assess the need for you to continue treatment after 6 months.

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

If you take more than the recommended number of tablets, even if you do not notice any problems, please contact your doctor.

#### **If you forget to take Targaxan**

Take the next dose at its normal time. Do not take a double dose to make up for a forgotten tablet.

#### **If you stop taking Targaxan**

Do not stop taking Targaxan without talking to your doctor first because your symptoms may return.

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 taking Targaxan and tell your doctor IMMEDIATELY if you have any of the following side effects:**

*Uncommon (may affect up to 1 in 100 people):*

- If you have bleeding from swollen blood vessels in your throat (oesophageal varices).
- If you have severe diarrhoea during or after using this medicine. This may be due to an infection of the intestine.

*Not known (frequency cannot be estimated from the available data):*

- If you get an allergic reaction, hypersensitivity or angioedema. Symptoms include:
  - swelling of the face, tongue or throat
  - swallowing difficulties
  - hives and breathing difficulties.
- If you have any unexpected or unusual bleeding or bruising. This may be due to a decrease in the platelets in your blood which increases the risk of bleeding. Frequency is not known (cannot be estimated from the available data).

#### **Other side effects that may occur**

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

- Depressed mood
- Dizziness
- Headache
- Shortness of breath
- Feeling or being sick



- Stomach ache or bloating/swelling
- Diarrhoea
- Accumulation of fluid in the abdominal cavity (ascites)
- Rash or itching
- Muscle cramps
- Joint pain
- Swelling of ankles, feet or fingers

*Uncommon (may affect up to 1 in 100 people):*

- Yeast infections (such as thrush)
- Urinary infection (such as cystitis)
- Anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- Loss of appetite
- Hyperkalaemia (high level of potassium in the blood)
- Confusion
- Anxiety
- Feeling sleepy
- Difficulty sleeping
- Feeling unsteady
- Loss of or poor memory
- Loss of concentration
- Reduced sense of touch
- Convulsions (fits)
- Hot flushes
- Fluid around the lungs (pleural effusion)
- Abdominal pain
- Dry mouth
- Muscle pain
- Needing to pass urine more often than usual
- Difficulty or pain passing urine
- Fever
- Oedema (swelling due to too much fluid in the body)
- Falls

*Rare (may affect up to 1 in 1,000 people):*

- Chest infections including pneumonia
- Cellulitis (inflammation of tissue under skin)
- Upper respiratory tract infections (nose, mouth, throat)
- Rhinitis (inflammation inside the nose)
- Dehydration (body water loss)
- Changes in blood pressure



- Constant breathing problems (such as chronic bronchitis)
- Constipation
- Back pain
- Protein in the urine
- Feeling weak
- Bruising
- Pain following surgery

*Not known (frequency cannot be estimated from the available data):*

- Fainting or feeling faint
- Skin irritation, eczema (itchy, red, dry skin)
- Reduction in platelets (seen in the blood)
- Changes in the way the liver is working (seen in blood test)
- Changes in blood coagulation (International Normalised Ratio seen in blood test)

**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) 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 TARGAXAN**

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

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

Targaxan does not require any special storage conditions.

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

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

**What Targaxan contains**

The active substance is rifaximin. Each tablet contains 550 mg rifaximin.

The other ingredients are:

- Tablet core: sodium starch glycolate (Type A), glycerol distearate, colloidal anhydrous silica, talc, microcrystalline cellulose.
- Tablet coat (opadry oy-s-34907): hypromellose, titanium dioxide (E171), disodium edetate, propylene glycol, red iron oxide (E172).



**What Targaxan looks like and contents of the pack**

Pink oval curved film-coated tablets marked with “RX” on one side.

Targaxan is available in cartons of 14, 28, 42, 56 and 98 tablets.

Not all pack-sizes may be marketed.

**Marketing Authorisation Holder:**

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

**Manufacturer:**

Alfasigma S.p.A.  
Via E. Fermi, 1 - 65020 Alanno (PE), ITALY

Or

Alfasigma S.p.A.  
Via Pontina Km 30,400 - 00071 Pomezia (Roma), ITALY

**This leaflet was last revised in 12/2020**

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

TARGAXAN®: Belgium, Finland, Ireland, Luxembourg, United Kingdom

XIFAXAN®: Denmark, Germany, Netherlands, Norway, Sweden.

**Other sources of information**

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