

PACKAGE LEAFLET:  
INFORMATION FOR THE USER

# Arelix<sup>®</sup>

## 6 mg Tablets

Piretanide



### Is this leaflet hard to see or read? Phone 01 403 5600 for help

**Read all of this leaflet carefully before you start using this medicine**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

**In this leaflet:**

1. What Arelix Tablets are and what they are used for
2. Before you take Arelix Tablets
3. How to take Arelix Tablets
4. Possible side effects
5. How to store Arelix Tablets
6. Further information

#### 1. What Arelix Tablets are and what they are used for

**What Arelix Tablets are**

The name of your medicine is Arelix 6mg Tablets (called Arelix Tablets throughout this leaflet). Arelix Tablets contain 6mg piretanide. Arelix Tablets belong to a group of medicines called diuretics (water tablets).

**What Arelix Tablets are used for**

Arelix Tablets are used to help you lose extra water in your body very quickly. They are given when you have a lot of extra water in your body. They are also used to lower your blood pressure if it is too high.

**How Arelix Tablets work**

Arelix Tablets work by helping you to pass more water (urine) than you usually do. If the extra water in your body is not removed, it can put extra strain on the heart, blood vessels, lungs, kidneys or liver.

#### 2. Before you take Arelix Tablets

**Do not take this medicine and tell your doctor if:**

- You are allergic (hypersensitive) to piretanide or any of the other ingredients of Arelix Tablets (listed in Section 6 below).  
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You are allergic to sulphonamides
- You suffer from kidney or liver problems
- Your doctor has told you that you have a low blood volume or are dehydrated
- You are not passing any water (urine)
- You have too little potassium or sodium in your blood (shown in blood tests)
- You are breast-feeding (see “Pregnancy and breast-feeding” section below) Arelix Tablets should never be given to children.

Do not take Arelix Tablets if any of the above apply to you. If you are not sure, talk to your doctor or nurse before taking Arelix Tablets.

**Take special care with Arelix Tablets**

**Check with your doctor or nurse before you take this medicine if:**

- You have difficulty in passing water (urine)
- You are 65 years of age or older
- You have liver or kidney problems
- You have severe hardening /narrowing of the arteries to the brain (cerebral sclerosis) or heart (coronary sclerosis)
- You have diabetes
- You have low blood pressure or feel dizzy when you stand up
- You have prostate problems
- You have gout
- You feel dizzy or dehydrated. This can happen if you have lost a lot of water through being sick, having diarrhoea or passing water very often. It can also happen if you are having trouble drinking or eating

If you are not sure if any of the above apply to you, talk to your doctor or nurse before taking Arelix Tablets.

The use of Arelix can produce positive results in doping tests. In addition, the use of Arelix as a doping agent can endanger health.

**Taking other medicines**

Please tell your doctor or nurse if you are taking or have recently taken any other medicines.

This includes medicines you buy without a prescription, including herbal medicines.

This is because Arelix Tablets can affect the way some other medicines work. Also, some medicines can affect the way Arelix Tablets work.

**In particular, tell your doctor if you are taking any of the following:**

- Medicines for your heart (called ‘ACE Inhibitors’). Your doctor may need to change the dose of your tablets or ask you to stop taking them
- Medicines used as a general anaesthetic for relaxing your muscles during surgery
- Medicines for diabetes. These may not work as well when you are using Arelix Tablets
- Lithium – used for mental illnesses. To help stop side effects your doctor may need to change the dose of your lithium and check the amount of lithium in your blood
- Medicines used for heart problems (e.g. digoxin or digitalis). Your doctor may need to change the dose of your medicine
- Non-steroidal anti-inflammatory drugs (NSAIDs) – used for pain and inflammation
- Corticosteroids – used for inflammation
- Cisplatin – used for some cancers
- Carbenoxolone – used for ulcers of the food-pipe (gullet)
- Liquorice – often used in cough medicines if taken in large amounts
- Probenecid (used in treatment of gout and with HIV medications)
- Some medicines for infection (antibiotics which belong to the groups called aminoglycosides, cephalosporins, polymyxins)
- Medicines used for constipation (laxatives) if used for a long time
- Other water tablets (diuretics). Your doctor may need to change the dose of your medicine

**Pregnancy and breast-feeding**


Do not take Arelix Tablets if you are pregnant. Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you might be pregnant. Do not breast-feed if you are taking Arelix Tablets. This is because small amounts may pass into the mother’s milk. Ask your doctor or nurse for advice before taking any medicine if you are pregnant or breast-feeding.

**Driving and using machines**

You may feel dizzy or unwell after taking Arelix Tablets. If this happens, do not drive or use any tools or machines.

#### 3. How to take Arelix Tablets

Follow your doctors direction about when and how to take your medicine and look at the label. Your pharmacist may also help if you are not sure.

DATE: 16/04/2015	CODE SAP/ID N°: 89028844	REPLACED CODE SAP/ID N°: 89026305	VERSION: 3	BRILLE: Justella num.
DESCRIPTION: 1ST ARELIX 6MG IE 101	TECHNICAL DRAW. CODE: 62C0005	EXT. DIM.: 167 x 304,8 s	PROOF N°: 3	PACKAGING LINE: -
PACK. ITEM: Istruzione	LAETUS: 0011001100	DIE CUT: -	PRODUCT LOGO: -	MIN. FONT SIZE: 9 su 9 pt
MARKET: IE: IRELAND	COLOURS: ■ Reflex Blue	IMPIANTO DI PROPRIETÀ: Sanofi S.p.A.	PAGE: 1 / 2	
Text approval Date: _____	Signature: _____	 <b>Arkhe S.n.c.</b> Tel. 0862.404140 fax 0862.404140		
Final approval Date: _____	Signature: _____			
Verificare la corrispondenza delle pellicole con l'etichetta apposta. - La nostra responsabilità è limitata al rifacimento delle eventuali pellicole errate.				

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#### Fluid Retention (oedema):

- The usual dose for patients with fluid retention is 6 mg daily.
- A starting dose of 3mg is given to some patients.
- Your doctor may adjust your dose to a maximum of 30mg.

#### High Blood Pressure:

- The usual starting dose for patients with high blood pressure 6mg daily.
- The dose will be continued for 2-4 weeks.
- If necessary your doctor will increase your dose at 2-4 week intervals to a maximum dose of 18 mg daily.
- The usual daily dose is 6 mg daily.

If you are elderly you may start off taking a lower dose.

Swallow your tablets with a glass of water.

The tablet can be divided into equal doses (3mg each) along the score line.

To divide tablet, hold the tablet, facing upwards, with both hands on either side of the score, between the thumb and the index finger of each hand. Without inserting a fingernail into the score, break the tablet in two by a circular movement with the index fingers.

#### If you take more Arelix Tablets than you should

If you take more Arelix Tablets than you should contact your doctor immediately or consult with your nearest hospital casualty department.

#### If you miss a dose of Arelix Tablets

If you miss a dose, take it as soon as you remember unless it is nearly time for your next dose. Never double-up on the next dose to make up for the one missed.

#### If you stop taking Arelix Tablets

Keep taking Arelix Tablets until your doctor tells you to stop.

#### 4. Possible side effects

Like all medicines, Arelix Tablets can cause side effects, although not everybody gets them.

#### Tell your doctor or nurse straight away if you notice any of the following serious side effects – you may need urgent medical treatment

- If you have an allergic reaction. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
  - Bruising more easily, getting more infections, feeling weak or tired more than usual. Arelix Tablets can affect the number of blood cells, causing serious blood problems.
  - Increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, stomach upsets or uneven heartbeats.
- These could be signs of dehydration or changes in your normal body chemicals. Severe dehydration can lead to blood clots (thrombosis) or 'gout'.

#### Tell your doctor as soon as possible if you have any of the following side effects:

- Problems hearing or ringing in the ears (tinnitus). This especially affects people who already have problems with their kidneys
- Headaches, feeling dizzy or light-headed when standing up quickly. Also loss of concentration, slower reactions, feeling sleepy or weak, problems with your sight, dry mouth. This could be due to low blood pressure
- Fever, chills, tiredness, loss of appetite, stomach pain, feeling sick (nausea), yellowing of your skin or eyes (jaundice). These can be signs of liver problems such as hepatitis (inflammation of the liver), cholangitis (inflammation of the bile duct) or liver damage.
- Inflammation of your blood vessels (vasculitis). Symptoms may include fever, loss of appetite, weight loss, aches and pains.
- Difficulty in passing water (urine), particularly if you have an enlarged prostate gland.
- Impotence (difficulty getting or maintaining an erection). This could be due to low blood pressure.
- High temperature (fever)

#### Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet

- Feeling sick (nausea) or a general feeling of being unwell, diarrhoea and being sick (vomiting)
- If you have diabetes you may be less able to control the levels of glucose in your blood
- Passing more water (urine) than you usually do. This normally happens 1 or 2 hours after taking this medicine
- If any of the side effects get serious, or if 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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie)

E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Arelix Tablets

Keep out of the reach and sight of children. Do not take your medicine after the expiry date shown on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package, to protect from light. Piretanide is light sensitive.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. Further information

##### What Arelix Tablets contain

The active ingredient in this medicine is piretanide. Each tablet contains 6mg piretanide. The other ingredients are maize starch, microcrystalline cellulose, colloidal anhydrous silica and magnesium stearate.

##### What Arelix Tablets looks like and contents of the pack

Arelix 6mg Tablets are yellowish-white, oblong scored tablets and are available in blister packs of 20 and 100 tablets. Not all pack sizes may be marketed.

##### Marketing Authorisation Holder and Manufacturer

###### Marketing Authorisation Holder

sanofi-aventis Ireland Ltd., T/A SANOFI,  
Citywest Business Campus  
Dublin 24  
Ireland  
Tel: +353 1 403 5600  
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Email: [IEmedinfo@sanofi-aventis.com](mailto:IEmedinfo@sanofi-aventis.com)

###### Manufacturer(s)


Sanofi S.p.A  
SS 17km 22,  
67019 Scoppito  
Italy

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or nurse.

This leaflet was last revised in March 2015.

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