

Arret® 2 mg Hard Capsules

loperamide hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- This medicine is used to treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 12 years and over.
- **Do not take this medicine:**
 - There are some people who should not use this medicine. To find out if you are one of them. See Section 2 ▶
 - If you are allergic to loperamide or any of the other ingredients of this medicine.
- **Speak to your doctor:**
 - If you suffer from any of the conditions mentioned in Section 2 ▶
 - If you are taking any other medicines. See Section 2 ▶
- **Follow the dosage instructions carefully.** These are shown in the dosage table. See Section 3 ▶

Now read this whole leaflet carefully before you use this medicine.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your pharmacist. This includes any possible side effects not listed in this leaflet. See section 4 ▶
- You must talk to a doctor if you do not feel better or if you feel worse after 24 hours.

What is in this leaflet

1. What ARRET Capsules are, and what they are used for.
2. What you need to know before you take ARRET Capsules.
3. How to take ARRET Capsules.
4. Possible side effects.
5. How to store ARRET Capsules.
6. Contents of the pack and other information.

1. What ARRET Capsules are and what they are used for

ARRET Capsules is a medicine which is used to treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 12 years and over.

The capsules contain loperamide hydrochloride which helps reduce diarrhoea by slowing down an overactive bowel, which helps the body to absorb water and salts from the bowel. ARRET Capsules should be used in conjunction with oral rehydration therapy which replaces fluids and salts lost during diarrhoea.

2. What you need to know before you take ARRET Capsules

This medicine is suitable for most people, but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

Do not take ARRET Capsules:

- If you are allergic to loperamide or any of the other ingredients of this medicine (listed in section 6)
- If it is for a **child under 12 years old**.
- If you have **severe diarrhoea** after taking antibiotics.
- If you are having a flare up of an **inflammatory bowel** condition like **ulcerative colitis**.
- If you are **constipated** or your **stomach appears swollen** (particularly in children with severe dehydration).
- If you have **acute dysentery**, the symptoms of which may include **blood in your stools** and a **high temperature**.
- If you have had a **bacterial infection** of the small intestine or colon.
- If you have a **blockage of the bowel**, including a blockage due to paralysis of the bowel wall.

- If you have an **enlargement of the colon**, particularly if this enlargement is very rapid.

If any of these apply to you, **get advice from a doctor or pharmacist without taking ARRET Capsules.**

Warnings and Precautions

Talk to your doctor or pharmacist before using ARRET Capsules.

- ARRET Capsules only treats the symptoms of diarrhoea. Whenever the cause can be identified, it should be treated appropriately.
- If you have **AIDS** and your **stomach becomes swollen**, stop taking the capsules immediately and contact your doctor.
- If you suffer from **liver problems**.
- If your diarrhoea lasts for **more than 24 hours**, please consult your doctor.
- Do not take this product for anything other than its intended use (see section 1) and never take more than the recommended amount (see section 3). Serious heart problems (symptoms of which include fast or irregular heartbeat) have been reported in patients who have taken too much loperamide, the active ingredient in ARRET Capsules.
- If you have been told by your doctor that you have an **intolerance to some sugars**.
- If you have **severe diarrhoea** as your body loses more fluid, sugars and salts than normal.

Other medicines and ARRET Capsules

- If you are taking any other medicines, including:
 - *ritonavir* (used to treat **HIV**) or *quinidine* (used to treat **abnormal heart rhythms** or **malaria**).
 - *itraconazole* or *ketoconazole* (**antifungal** medicines)
 - *gemfibrozil* (used to treat **high cholesterol**)
 - *oral desmopressin* (used to **control thirst** and **urine production** in patients with diabetic insipidus)

If you are unsure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist**.

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.
- Do not take this medicine if you are breast-feeding as small amounts may get into your milk. Talk to your doctor about a suitable treatment.

Driving and using machines

- This medicine may make you feel dizzy, tired or sleepy. If affected do not drive or operate machinery.

Other information about this medicine

- ARRET Capsules only treat the symptoms of diarrhoea. When you have diarrhoea, your body can lose large amounts of fluids and salts. You will need to replace the fluid by drinking more liquid than usual. Ask your pharmacist about special powders (known as **oral rehydration therapy**) which replace fluids and salts lost during diarrhoea. The prevention of fluid depletion (dehydration) is of particular importance in infants, children and frail and elderly people with acute diarrhoea.

Some of the ingredients can cause problems

- This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine.
- This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take ARRET Capsules

Check the tables below to see how much medicine to take.

- Swallow the correct number of capsules whole with a drink of water.
- For oral use only.
- Do not use more than the stated dose shown in the tables.

Children under 12 years old

Do not give to children under 12 years of age.

Adults and children 12 years and over

To treat sudden short-lived (acute) diarrhoea:

Age	Dose
Adults and children aged 12 years and over	Swallow two capsules initially, followed by one capsule after each loose bowel movement.
<ul style="list-style-type: none">– Do not take more than 5 capsules in any 24 hour period.– If symptoms persist for more than 24 hours talk to your doctor.	

Use in the elderly, patients with kidney or liver problems.

No dose adjustment is required for the **elderly** or patients with **kidney** problems. However, if you have **liver** problems you should speak to your doctor or pharmacist before taking this medicine.

If you take more ARRET Capsules than you should

If you have taken too many ARRET Capsules, immediately contact a doctor or hospital for advice. Symptoms may include: increased heart rate, irregular heartbeat, changes to your heartbeat (these symptoms can have potentially serious, life-threatening consequences), muscle stiffness, uncoordinated movements, drowsiness, difficulty urinating, or weak breathing. Children react more strongly to large amounts of ARRET Capsules than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.

If you forget to take ARRET Capsules

You should only take this medicine as required following the dosage instructions above carefully. If you forget to take a dose, take a dose after the next loose stool (bowel movement). **Do not** take a double dose.

4. Possible side effects

Like all medicines, ARRET Capsules can cause side effects, although not everybody gets them.

If you experience any of the following, stop using the medicine and seek immediate medical help:

- Allergic reactions including unexplained wheezing, shortness of breath, passing out or swelling of face and throat.
- Skin rashes which may be severe and include blistering or peeling of the skin.
- Loss of consciousness or reduced level of consciousness.

If you experience any of the following, stop using the medicine and talk to your doctor

Common: may affect up to 1 in 10 people

- Headache
- Constipation
- Nausea
- Flatulence

Uncommon: may affect up to 1 in 100 people.

- Dizziness or drowsiness.
- Feeling sick, vomiting and indigestion
- Tiredness
- Dry mouth
- Stomach discomfort
- Rash

Rare: less than 1 in 1,000 people are affected

- Itchiness or hives.
- Difficulties passing water.
- Stomach pain or swollen stomach.
- Severe constipation.
- Hypertonia (muscle tension).
- Miosis (constriction of the eye pupil).
- Ileus (blockage of the bowel, this may be due to paralysis of the bowel wall)
- Megacolon (enlargement of the colon, this may be rapid)

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 HPRAPharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ARRET Capsules

Do not store above 25 °C. Store in the original package.

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

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

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

6. Contents of the pack and other information

What ARRET Capsules contains

The active substance is loperamide hydrochloride. Each hard capsule contains 2 mg loperamide hydrochloride.

The other ingredients are: lactose monohydrate, maize starch, talc, magnesium stearate, titanium dioxide (E171), yellow ferric oxide (E172), indigotin, gelatin, erythrosine sodium.

What ARRET Capsules looks like and contents of the pack

Each hard capsule has a green cap and purple body and contains a white odourless powder

ARRET 2 mg Hard Capsules are available in blister packs of 6 and 12 capsules, contained in an outer cardboard carton. Not all pack sizes may be marketed.

Parallel Product Authorisation Number:

PPA 465/155/1

Manufacturer

Famar ABE (Plant B), Anthousis Avenue, 15344 Anthousa, Greece.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

ARRET is a registered trademark of Janssen-Cilag Ltd.

Date of leaflet preparation by PCO Manufacturing:

December 2018