PATIENT INFORMATION LEAFLET

APERCAP 0.2 ml GASTRO-RESISTANT CAPSULES

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However you still need to take Apercap 0.2 ml Gastro-Resistant Capsules carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your doctor if your symptoms worsen or do not improve after 14 days.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What is APERCAP and what is it used for?

Apercap Capsules are used to relieve the symptoms of irritable bowel syndrome (IBS).

These capsules are specially coated to allow them to pass intact through the stomach and the first part of the bowel. This allows the capsules to reach the part of the gut where they are needed. It is only then that the peppermint oil is released from the capsule to do its work.

wall. This reduces symptoms such as bloating, trapped wind, bowel discomfort and pain.

2. Before you take APERCAP

Do not take the capsules if:

- you are allergic to the peppermint oil, menthol or any of the other ingredients in the capsules (see section 6 'Further Information').
- · you suffer from inflammation of the bile duct, gallstones or any other bile disorders.
- · you suffer from a condition called 'achlorhydria' that prevents normal digestion of food.

Talk to your doctor first if any of the following apply to you and follow the advice given:

- this is the first time you have suffered from any of the symptoms such as bloating, trapped wind or bowel discomfort and pain.
- · you are over 40 years of age and you have not had this problem recently or if your symptoms appear to be different from before.
- · you are feeling sick, or have been sick.
- · you have a temperature or feel feverish.
- · vou have severe constipation.
- · you suffer from heartburn.
- you suffer from a hernia, specifically named 'hiatal hernia'.
- you have pain or difficulty when passing urine.
- · you are pale and tired.
- vou have lost vour appetite or lost weight.
- you have passed blood from your bowel.
- · you have unusual vaginal bleeding or discharge.
- · you have travelled abroad recently.

Are you pregnant or breast-feeding?

Tell your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant.

Tell your doctor if you are breast-feeding.

Taking other medicines

You should **not** take Apercap Capsules at the same time as;

- · medicines used for indigestion (antacids).
- · medicines used for stomach or intestinal ulcers and acid reflux (histamine-2 blockers and proton pump inhibitors).

It is unlikely Apercap Capsules will interfere with the action of any other medicines you may be taking. However, it may sometimes affect the clearance of some medicines from the body. Peppermint oil helps to restore normal bowel action by relaxing the muscle spasm in the bowel It is always sensible to tell your doctor and/or pharmacist what these medicines are – mention prescription medicines, or medicines, including vitamins and herbal preparations, that you have purchased yourself.

Driving and using machines

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

Apercap contains sodium

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

3. How to take APERCAP

Take the capsules by mouth with a drink of water. Swallow the capsules whole; do not chew

or break them because this will damage the special coating that enables them to get to the correct part of your bowel.

Do not take the capsules immediately after food.

The usual dose is:

Adults (including elderly people)

One capsule three times a day, before meals.

If your symptoms are severe, the dose may be increased to two capsules three times a day.

Children:

Apercap Capsules are not recommended for children.

Apercap Capsules are usually only needed for a short period to relieve symptoms. However, your condition does not improve after two weeks, you should consult your doctor who may decide to continue the treatment for up to three months.

If you take more capsules than you should:

If you have taken more Apercap Capsules than you should, contact your doctor, pharmacist, or hospital casualty department immediately.

Symptoms of overdose include severe stomach upset, diarrhoea, rectal ulcers, fits, loss of consciousness, difficulty in breathing, feeling of sickness and abnormal beating of the heart.

If you miss a dose of Apercap Capsules:

Wait and take the next dose at the normal time.

4. Possible side effects

In some people, the following side effects have occurred:

- allergic reactions (rash, itchiness or shortness of breath)
- headache
- slow heartbeat
- · trembling
- unsteadiness
- · skin rash
- heartburn
- · itching around the back passage
- blurred vision
- feelings of sickness (nausea)
- vomiting
- · urine and stools with an odour to menthol
- · pain or difficulty when passing urine
- · inflammation of part of the penis

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. 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. Storing APERCAP

Keep Apercap Capsules out of the reach and sight of children. Do not store above 25°C.

There is an expiry date (Month/Year) on the pack. The capsules should not be used after the end of the month shown.

6. Further Information

The name of your medicine is Apercap 0.2 ml Gastro-Resistant Capsules. As well as containing 0.2 ml of peppermint oil, each capsule contains gelatin, glycerol, purified water, titanium dioxide powder (E171), chlorophyllin copper complex sodium (E141), aqua polish and propylene glycol.

Apercap 0.2 ml Gastro-Resistant Capsules are opaque, green and white, oval shaped, soft gelatine capsules containing a clear liquid.

Apercap 0.2 ml Gastro-Resistant Capsules are available in blister packs of 20, 28, 30 or 84 capsules. Not all pack sizes may be marketed.

Marketing Authorisation holder

Teva UK Limited

Ridings Point

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Manufacturer

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