

## Package leaflet: Information for the patient

### Ispagel® Orange Ispaghula Husk

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.

- 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 doctor or 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 3 days.

#### What is in this leaflet

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

#### 1. What Ispagel® Orange is and what it is used for

The name of your medicine is Ispagel® Orange. It contains the active ingredient ispaghula husk in the form of granules which, when dispersed in water, make an orange flavoured drink.

Ispaghula husk is a type of natural fibre that belongs to a group of medicines known as bulk-forming laxatives. It works by increasing the bulk of your stools, which encourages your bowels to move these stools through your digestive system, which in turn relieves constipation.

Ispagel® Orange is recommended wherever increased fibre is needed in your diet to help relieve constipation – this includes constipation during pregnancy. It is also recommended to help maintain a normal bowel function among patients suffering from any of the following conditions:

- irritable bowel syndrome
- colostomy or ileostomy
- haemorrhoids (piles)
- anal fissure
- persistent diarrhoea associated with diverticular disease
- ulcerative colitis.

#### 2. What you need to know before you take Ispagel® Orange

**Do not take Ispagel® Orange if you:**

- are allergic to ispaghula husk or any of the other ingredients of this medicine (listed in section 6)
- have severe pain, cramps or swelling in your abdomen, vomiting (being sick). You may have a blockage in your intestine
- have compressed and hardened faeces causing a blockage of the bowel (faecal impaction)
- have been told by your doctor that the muscles in the wall of your bowel are weak or not working
- have a disease called phenylketonuria (an inherited disorder of protein metabolism).
- have a sudden change in bowel habit that has lasted more than two weeks.
- have rectal bleeding that is undiagnosed.

- have failed to defecate following the use of a laxative.
- suffer from difficulty in swallowing or any throat problems.
- have any diseases related to oesophagus.
- Do not take if you are under 12 years old.

#### Warnings and precautions

- As per the instructions, always take Ispagel® Orange with plenty of water (see section 3). Taking it with too little water could cause it to stick in your gullet or throat, making it difficult for you to swallow or breath, to have pain in your chest or to be sick. If this happens seek urgent medical help.
- Make sure that you drink enough fluid during the day while you are taking this medicine (see 'Taking Ispagel® Orange with food and drink' below). If you are elderly or debilitated, you may need someone to help you do this.
- If you have been informed by your doctor that you have narrowing of the intestines or reduced bowel motility, talk to your pharmacist or doctor before taking Ispagel® Orange to make sure that it is suitable for you.
- If your constipation is not relieved or your symptoms persist longer than 3 days, consult your doctor or healthcare professional.
- Do not take the last dose of the day immediately before sleep as this can cause obstruction of the bowel.
- Do not take Ispagel® Orange if you are debilitated or elderly, unless your doctor tells you to.
- Do not take Ispagel® Orange with medicines that may reduce bowel motility (e.g. Opioids)
- Absorption of calcium, iron, vitamins and minerals from your digestive system may be reduced while taking this medicine.

#### Other medicines and Ispagel® Orange

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. In particular the following:

- Mineral or vitamin B 12 supplements
- Medicines for heart failure (cardiac glycosides)
- Medicines to thin the blood such as warfarin
- Lithium for bipolar disorder.
- Medicines to treat diabetes
- Medicines to treat Epilepsy such as carbamazepine
- Thyroid hormones

#### Taking Ispagel® Orange with food and drink

- Maintain an adequate fluid intake whilst taking this medicine by drinking enough water. You should aim to drink at least eight large glasses of water a day.
- To prevent constipation it is important to eat a well balanced diet containing fibre (whole grain breads and cereals, bran, fruit and green leafy vegetables) and to take daily exercise.

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- Drinks containing caffeine (tea, coffee) or alcohol can make constipation worse as they have a diuretic effect, which means they cause a loss of fluid from the body, causing dehydration.

#### Pregnancy and breast-feeding

There is no restriction to the use of Ispagel® Orange during pregnancy and breast-feeding.

#### Ispagel® Orange contains aspartame (E951) and sodium

This medicine contains 80.00 mg of aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicinal product contains 68.18 mg sodium per sachet, equivalent to approximately 3.5% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

### 3. How to take Ispagel® Orange

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

#### How to prepare Ispagel® Orange drink:



Put the contents of the sachet into an empty glass. Add 150ml of cold water.



Stir briskly for 3-5 seconds.



Drink straight away, preferably after meals.

#### The recommended dose is:

**Adults, the elderly and children over 12 years:** One sachet Ispagel® Orange in the morning and evening or as prescribed by your doctor.

**Children aged 12 years and under:** Ispagel® Orange should not be used in children aged 12 years and under. Other pharmaceutical forms may be more appropriate for administration to this population.

Do not take Ispagel® Orange without water.

If there has been no bowel movement after three days of treatment, consult your doctor.

#### If you take more Ispagel® Orange than you should

If you accidentally take too much of Ispagel® Orange, you may experience the following:

- abdominal pain
  - flatulence (passing excessive wind)
  - bowel obstruction (which would present with symptoms such as abdominal pain, swelling of abdomen, vomiting and constipation)
- Drink plenty of water and see your doctor straightaway.

#### If you forget to take Ispagel® Orange

If you forget to take a dose, just take your next dose as normal.

Do not take a double dose to make up for a forgotten dose.

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.

If you get any of the following side effects you should stop taking Ispagel® Orange and contact your doctor, as these may be signs of an allergic reaction to the medicine:

- a skin rash resembling hives (itchy, raised swollen areas on the skin) or nettle rash

- itchy or runny nose
- shortness of breath
- inflammation of the membrane that covers the inner surface of the eyelid (conjunctivitis).

You may experience flatulence (i.e. passing excessive gas/wind), Abdominal distension (i.e. abdominal swelling), faecal impaction (i.e. compressed and hardened faeces causing a blockage of the bowel) or abdominal discomfort during the first few days of taking Ispagel® Orange. These effects should lessen as you continue to take Ispagel® Orange.

#### 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 at: [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 Ispagel® Orange

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package.
- Do not use this medicine after the expiry date which is stated on the label after EXP. 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 Ispagel® Orange contains

- The active substance is Ispaghula husk. Each sachet contains 3.5 g of Ispaghula husk.
- The other ingredients are sodium bicarbonate, orange flavour 501071 AP0551 (maize maltodextrin, alpha-tocopherol (E307), flavouring components), beta-carotene, aspartame (E951), citric acid anhydrous, riboflavin-5-sodium phosphate

#### What Ispagel® Orange looks like and contents of the pack

Ispagel® Orange is available in single dose sachets containing effervescent granules, in cartons of 3, 5, 10, 30 or 60 sachets. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

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To request a copy of this leaflet in Braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.