

Important information. Please read carefully.

ConsiGel™

Powder for Oral Solution 3.5g

What is ConsiGel?

Description, Dosage form and Packaging

ConsiGel is a sugar-free high fibre drink containing natural soluble fibre, 3.5g of ispaghula husk in a sachet. This product comes in brown colour powder. After dissolved in water, it is a yellow to brownish suspension with brown speckles. The suspension is orange flavour. Available in a pack size of 10 sachets x 4.4g.

What is ConsiGel used for?

ConsiGel is recommended for the relief of constipation, including constipation in pregnancy and the maintenance of bowel regularity. This product also helps in the management of bowel function in patients with:

- Colostomy
- Ileostomy
- Haemorrhoids (piles)
- Anal fissure
- Chronic diarrhoea associated with diverticular disease
- Irritable bowel syndrome
- Ulcerative colitis

How ConsiGel works?

ConsiGel contains ispaghula husk (or psyllium husk) which is a natural fibre/ bulk laxative that helps to relieve constipation.

Pharmacodynamics

Ispaghula husk absorbs water in the gastrointestinal tract to form a mucilaginous mass which increases the volume of faeces and hence promotes peristalsis (muscle contractions) in the digestive tract.

Pharmacokinetics

Ispaghula husk hydrates and swells to form a mucilage because it is only partially solubilised. Polysaccharides, such as those which dietary fibres are made of, must be hydrolysed to monosaccharides before intestinal uptake can occur. The sugar residues of the xylan backbone and the side chains are joined by β-linkages, which cannot be broken by human digestive enzymes. Less than 10% of the mucilage gets hydrolysed in the stomach, with formation of free arabinose. Intestinal absorption of the free arabinose is approximately 85% to 93%. To varying degrees, dietary fibre is fermented by bacteria in the colon, resulting in production of carbon dioxide, hydrogen, methane, water, and short-chain fatty acids, which are absorbed and brought into the hepatic circulation. In humans, such fibre reaches the large bowel in a highly polymerised form that is fermented to a limited extent, resulting in increased faecal concentration and excretion of short-chain fatty acids.

How to consume ConsiGel?

ConsiGel is intended for oral use as a suspension in a full drink of water. The granules should be stirred into a glass of water and taken as soon as possible, preferably after meals. The effects start 12 - 24 hours later.

This product should be taken during the day at least ½ to 1 hour before or after intake of other medicines and should not be taken immediately before going to sleep.

When preparing the product for administration, it is important to try to avoid inhaling any of the powder in order to minimize the risk of sensitisation to the active ingredient.

Adults & Children over 12 years old

One sachet, in the morning and evening

Children (6 - 12 years old)

Half to one level 5 ml spoonful, depending on age and weight, in the morning and evening

Children (under 6 years old)

The use in children under 6 years of age is not recommended

Contraindications

Ispaghula husk should not be taken if you have pre-existing faecal impaction (excessive stool straining), intestinal obstruction, or colonic atony (weak colon muscle).

Precautions

- The product should not be taken dry and should always be taken mixed with fluid (8 fluid ounces or 240 ml of water or other liquid per sachet). Please consume a large amount of fluid/water when taking this product.
- ConsiGel should not be used by patients with faecal impaction and symptoms such as abdominal pain, nausea and vomiting unless advised by a doctor because these symptoms can be signs of potential or existing intestinal blockage (ileus).
- If abdominal pain occurs or in cases of any irregularity of faeces, the use of ConsiGel should be discontinued and medical advice must be sought.
- When taken with inadequate fluid amounts, bulk forming agents can cause obstruction of the throat and oesophagus with choking and intestinal obstruction. Symptoms can be chest pain, vomiting, or difficulty in swallowing or breathing.
- The treatment of debilitated patients and / or elderly patients requires medical supervision.



- In order to decrease the risk of gastrointestinal obstruction, ConsiGel should not be used together with medicinal products known to inhibit peristaltic movement (e.g. opioids). Consumption of ConsiGel with medicinal products must be taken under medical supervision.
- The last dose should not be taken immediately before going to sleep since impaired or reduced gastric motility may impair the intestinal passage and may cause sub-obstruction.
- If the constipation does not resolve within 3 days or if abdominal pain occurs or in case of any irregularity of faeces, the use of psyllium (ispaghula husk) should be discontinued and medical advice must be sought.

Pregnancy and Lactation

ConsiGel may be considered during pregnancy and lactation, if necessary and if change of nutrition is not successful. Laxative bulk producers should be used before using other purgatives.

Interactions with Other Medicaments

Ispaghula and other bulk-forming laxatives may delay or reduce the gastrointestinal absorption of other drugs such as cardiac glycosides, coumarin derivatives, lithium, or vitamins (such as vitamin B12) and minerals (such as calcium, iron or zinc).

Intervals of 30 minutes to 1 hour are recommended between ispaghula and other drugs or food.

The dose of insulin may need to be reduced in diabetic patients taking ispaghula.

Does ConsiGel have side effects?

Hypersensitivity reactions reported include rash, rhinitis (nose inflammation), urticaria (skin swelling with hives), bronchospasm (airway congestion), and anaphylactic shock (serious allergic reaction).

What to do if you have consumed ConsiGel more than the recommended dose?

In case of overdose, seek medical attention immediately.

You may experience abdominal discomfort, flatulence and intestinal obstruction. Adequate fluid intake should be maintained, particularly if the granules have been taken without water contrary to administration instructions, and management should be symptomatic.

How should you keep ConsiGel?

Store below 30 °C. Keep out of reach of children.

The expiry date of this product is indicated on the packaging.

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Manufacturer and Product Registration Holder (in Malaysia)

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