



PACKAGE LEAFLET: INFORMATION FOR THE USER

Manevac[®]

(Ispaghula Seed, Ispaghula Husk and Tinnevelly Senna Pods)

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 have 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 feel worse, or do not feel better after 7 days.

What is in this leaflet:

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

1. What Manevac is and what it is used for

Manevac is one of a group of medicines called laxatives. The medicine contains Ispaghula Seed, Ispaghula Husk (bulk-forming laxatives) and Tinnevelly Senna Pods (a stimulant laxative). Manevac is for short term use in the following: occasional constipation (infrequent passing of hard stools), to maintain normal bowel action in bed-ridden patients and to help reduce pain when emptying the bowels for patients suffering from haemorrhoids (piles). Manevac does not help with weight loss.

2. What you need to know before you take Manevac

Do not take Manevac if you:

- are allergic to Ispaghula Seed, Ispaghula Husk, Tinnevelly Senna Pods or any of the other ingredients of this medicine (listed in section 6).
- have a sudden change in bowel habit that has persisted for more than 2 weeks
- have undiagnosed rectal bleeding for which you don't know the cause, or blood in your stools
- have already taken a laxative and are still constipated
- have difficulty in swallowing or any throat problems
- have a blocked or narrowing of the gastrointestinal tract or bowel (ileus, intestinal obstruction, faecal impaction or stenosis)
- have paralysis or lack of muscle tone in the bowel wall (atony)
- have appendicitis or suffer from any bowel disorders, for example inflammatory bowel disease such as ulcerative colitis, Crohn's disease, or enlarged bowel (megacolon)
- have naturally occurring reduced gut motility (speed with which material moves through your gut has always been slow)
- are severely dehydrated
- have unexplained or persistent tummy complaints e.g. pain, nausea or vomiting
- have heart or kidney problems
- are under 12 years of age.
- are pregnant or breast feeding

Talk to your doctor before taking this product if any of the above applies to you.

Warnings and precautions

Take each dose of Manevac with 1-2 glasses of water or similar drink, such as milk or fruit juice. Taking Manevac without enough liquid can cause blockage of the throat and oesophagus (gullet) with choking and intestinal blockage. Symptoms can be chest pain, vomiting, or difficulty in swallowing or breathing. If you have chest pain, vomit, or have difficulty in swallowing or breathing after taking Manevac, get medical attention straight away. (See "How to take Manevac" in section 3.)

- Do not exceed the stated dose.
- Make sure you drink enough fluid while taking Manevac. This will also help your constipation.
- If the constipation does not resolve within 3 days, or if abdominal pain or rectal bleeding occurs, or if your stools are different in some way e.g. there is blood in your stools, stop taking Manevac and see your doctor.

- To decrease the risk of gastrointestinal blockage (ileus) Manevac should only be used with medicinal products known to inhibit bowel movement (e.g. opioids,) under medical supervision.
- Manevac contains potent allergens. As a consequence, after oral use or contact with the skin, Manevac may cause hypersensitivity (allergic) reactions (see section 4)

Talk to your doctor or pharmacist before taking Manevac if you:

- are weak, frail or elderly (you will need to be monitored while taking Manevac)
- have a blocked bowel (dried, hard stools with tummy pain, nausea and vomiting).
- have been informed by your doctor that you have narrowing of the intestines or reduced bowel motility

Take special care

- See your doctor if you need to use laxatives every day for your constipation. Do not use laxatives for a long time unless your doctor tells you. Using stimulant laxatives (such as Senna pods) more often than occasionally can slow down your bowel and make your constipation worse (called 'lazy bowel syndrome'- See Section 3 "If you take more Manevac than you should").
- If you are incontinent, your pads should be changed more frequently.
- You should first try taking more exercise, changing your diet or taking bulking agents to relieve your constipation before taking laxatives. Ask your pharmacist or doctor for advice.

Does this help with weight loss?

Stimulant laxatives (including Senna pods) do not help with weight loss. They do not reduce the absorption of calories or nutrients. They can cause watery stools (diarrhoea), abdominal cramps and dehydration. Dehydration can seem like weight loss.

Overuse of laxatives may damage your health by:

- Causing disturbances of electrolyte and mineral balances. Sodium, potassium, magnesium, and phosphorus are electrolytes and minerals that are present in very specific amounts necessary for proper functioning of the nerves and muscles, including those of the colon and heart. Upsetting this delicate balance can cause incorrect functioning of these vital organs.
- Severe dehydration may cause tremors, weakness, blurry vision, fainting, kidney damage, and, in extreme cases, death. Dehydration often requires medical treatment.
- Overuse of laxatives can cause the colon to stop reacting to usual doses of laxatives so that larger and larger amounts of laxatives may be needed to produce bowel movements.
- Laxative dependency occurs from overuse.

Other medicines and Manevac

Do not take with medicines which may reduce bowel motility (eg codeine and morphine).

Do not take Manevac within ½ to 1 hour before or after taking any medicines including those listed below.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular tell your doctor or pharmacist about:

- mineral or vitamin B12 supplements
- medicines for heart failure (cardiac glycosides)
- medicines to thin the blood such as warfarin
- carbamazepine for epilepsy (fits)
- lithium for bipolar disorder.
- insulin - If you are diabetic and use insulin, you may need to reduce your dose of insulin if you take Manevac with meals. Please discuss with your doctor if you have any concerns regarding this.
- medicines for thyroid problems - your doctor may need to change the dose of the thyroid hormones you are taking.
- medicines for heart failure or heart rhythm (e.g. cardiac glycosides, antiarrhythmic medicines e.g. quinidine, medicines inducing QT prolongation)
- water tablets (diuretics)
- certain steroids used for inflammation (adrenocorticosteroids)
- liquorice root.

Long term use of laxatives may increase the side effects of some medicines.

If any of the above applies to you, your doctor or pharmacist will be able to advise you further.

Pregnancy and breast-feeding

Do not take Manevac if you are pregnant or breast-feeding.

Driving and using machines

Manevac has no known effect on your ability to drive and use machines.

Important information for patients with an intolerance to some sugars

Manevac contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Manevac

If this product has been prescribed by your doctor, the label on the pack will tell you how much you should take and when. Always take Manevac exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure about taking Manevac.

Before taking this product, sit in an upright position. The granules should be taken using the measuring spoon included in the pack. Manevac should be placed dry on the tongue and, without chewing or crushing, swallowed with plenty of water, warm drink, milk, fruit juice, or similar liquid (approximately 1-2 glasses with each level measuring spoon).

Drink about 5-10 glasses of fluid every day while you are taking this product.

Dose

Adults the elderly and children over 12 years

The usual dose for adults, the elderly and children over 12 years is one (5g) or two (10g) level measuring spoons to be taken once daily at night.

Do not take this medicine immediately before bedtime.

Take the dose at least ½ to 1 hour before or after taking other medicines.

Take the smallest dose to produce comfortable soft stools.

The maximum daily dose of Manevac is two level measuring spoons (10g of granules).

You should not take Manevac for more than one week. Usually it is sufficient to take this medicinal product up to two to three times during that week. If the symptoms worsen or persist while using Manevac, if you need to take laxatives every day or if abdominal pain persists, talk to your doctor or a pharmacist. (See "Take special care with Manevac" in section 2.)

Do not take more than the leaflet tells you. Overuse can be dangerous.

Use in children and adolescents

Manevac is not recommended for children under 12 years of age.

If you take more Manevac than you should

If you take too much Manevac contact your nearest casualty department or tell your doctor or pharmacist immediately. Take this leaflet and any remaining granules with you.

It may be harmful to

- Take too much Manevac or
- Take Manevac for too long

This is because taking too much for too long may lead to:

- A 'lazy bowel', where the muscle in the bowel becomes too relaxed. This means that bowel emptying happens less often. This can lead to long-term constipation.

- Imbalance of fluid and salts in the body. This can affect the tightness of muscles such as those in the bowel. It can also affect the salts in the blood.

- Low levels of potassium in the blood (called 'hypokalaemia').

This can make you tired, dizzy, make your muscles weak and cause an uneven heart-beat.

Dehydration, making you thirsty, feel faint and giving you headaches. It can also mean you cannot pass enough urine.

If you forget to take Manevac

If you forget to take Manevac, just take your normal dose as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, 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 Manevac and seek medical advice immediately as these may be **signs of an allergic reaction** to the medicine:

- Anaphylactic reactions – severe and potentially life-threatening reaction with symptoms that may include feeling lightheaded or faint, breathing difficulties or wheezing, a fast heartbeat, skin rash, confusion, anxiety or loss of consciousness

- difficulty breathing including shortness of breath
- rhinitis (nasal obstruction or congestion)
- conjunctivitis
- chest tightness, wheezing
- asthma or worsening of asthma symptoms
- a skin rash resembling hives (itchy, raised, swollen areas on the skin) or nettle rash, itchiness or redness in one part of the body or more widespread

Other side effects that may occur include:

- Flatulence (wind) which may occur for a short time after starting Manevac.
- Nausea and vomiting.
- Tummy pain, tummy cramps and runny stools, in particular in patients with irritable bowel. However, these symptoms may also occur if too much Manevac has been taken. If this is the case, a reduced dose may be necessary.
- Swollen tummy, blockage in the throat or gut, difficulty swallowing and blocked bowel (dried, hard stools collected in the rectum and anus) may occur, particularly if insufficient fluid is drunk.
- Chronic use may lead to albuminuria and hematuria which is albumin or red blood cells in the urine.
- Yellow or red-brown discoloration of urine may occur which is harmless.
- Chronic use may cause pigmentation of the gastrointestinal tract which usually recedes when the product is no longer taken.
- The frequency of these side effects is not known.

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 Yellow Card Scheme (Website: www.yellowcard.mhra.gov.uk) or search for MHRA Yellow Card in 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 Manevac

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

Do not use Manevac after the expiry date, which is stated on the pack. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not use this medicine if you notice description of the visible signs of deterioration.

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 to protect the environment.

6. Contents of the pack and other information

What Manevac contains

The active substances are Ispaghula Seed, Ispaghula Husk and Tinnevelly Senna Pods.

Each 5g dose contains:

2.6g of Ispaghula Seed (*Plantago ovata* Forssk.);

0.11g of Ispaghula Husk (*Plantago ovata* Forssk.);

0.34-0.66g of Tinnevelly Senna fruit (*Cassia angustifolia* Vahl) corresponding to 15mg hydroxyanthracene glycosides calculated as sennoside B.

The other ingredients are caraway oil, Spanish sage oil, peppermint oil, acacia, talc, iron oxides (E172), hard paraffin, liquid paraffin and sucrose.

What Manevac looks like and contents of the pack

Manevac is presented as brown sugar-coated granules and is available in packs containing 400g of granules

Marketing Authorisation Holder

Mylan Products Ltd. Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

Madaus GmbH
51101 Koeln Cologne
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Manevac is a registered Trade Mark

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