PACKAGE LEAFLET: INFORMATION FOR THE USER

Manevac 12 Years Plus

(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 3 days.

What is in this leaflet:

- What Manevac 12 Years Plus is and what it is used for
- What you need to know before you take Manevac 12 Years Plus
- How to take Manevac 12 Years Plus
- Possible side effects
- How to store Manevac 12 Years Plus
- Contents of the pack and other information

What Manevac 12 Years Plus is and what it is used for

Manevac 12 Years Plus 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 12 Years Plus can be used for the short-term relief of occasional constipation.

Manevac 12 Years Plus does not help with weight loss.

What is constipation?

Normal and regular bowel movement is important for most people. However, what is "normal and regular" varies from person to person. Some may have a bowel movement every day, others less often. Whatever it is like for you, it is best that your bowel movement has a regular pattern. Constipation is an occasional problem for some people, for others it may happen more often. It happens when the normal muscle actions in the bowel (large intestine) slow down. This can mean that material is not easily eliminated from the body.

The cause of constipation is often not known. It can be associated with:

- Sudden change of diet
- A diet with not enough fibre
- Not drinking enough fluids
- Loss of 'tone' of the bowel muscles in older people
- **Pregnancy**
- Medicines such as morphine or codeine
- Having to stay in bed for a long time
- Lack of exercise

Whatever the cause, constipation can be uncomfortable. It may make you feel bloated and heavy or generally "off colour". Sometimes it causes headaches.

It is recommended to use changes in diet and bulk forming medicines to control constipation before using this medicine.

These healthy tips are recommended to try to prevent constipation happening:

- Eat a balanced diet including fresh fruit and vegetables
- Drink enough water so that you do not become dehydrated
- Keep up your exercise and stay fit
- Make time to empty your bowels when your body tells you

2. What you need to know before you take Manevac 12 Years Plus Do not take Manevac 12 Years Plus

- 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). if you have a sudden change in bowel habit that has persisted for more than 2 weeks
- if you 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
- if you have difficulty in swallowing or any throat problems
- if you 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)
- if you 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)
- If you are severely dehydrated
- have unexplained or persistent tummy complaints e.g. pain, nausea or vomiting
- have heart or kidney problems
- if you are children under 12 years of age.
- If you 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 12 Years Plus with 1-2 glasses of water or similar drink, such as milk or fruit juice. Taking Manevac 12 Years Plus 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 12 Years Plus, get medical attention straight away. (See "How to take Manevac 12 Years Plus" in section 3.)
- Do not exceed the stated dose.
- Make sure you drink enough fluid while taking Manevac 12 Years Plus. This will also help your constipation.
- If the constipation does not resolve within 3 days, or if abdominal (tummy) 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 12 Years Plus and see your doctor.
- To decrease the risk of gastrointestinal blockage (ileus) Manevac 12 years plus should only be used with medicinal products known to inhibit bowel movement (e.g. opioids,) under medical supervision.
- Manevac 12 Year Plus contains potent allergens. As a consequence, after oral use or contact with the skin, Manevac may cause hypersensitivity (allergic) reactions (see
- 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 12 Years Plus 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 12 Years Plus Do not take with medicines which may reduce bowel motility (eg codeine and morphine). Do not take Manevac 12 Years Plus 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 12 Years Plus 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

VIATRIS								
Description	Manevac Granules, (2.60 g	-0.11 g-0.34-0.66 g)/5 g, (2.0	60 g/0.11 g/0.34-0.66 g)/5 g, 250 g	Date: 21 JU	LY 2023	Time: 11:42		
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TrackWise/GLAMS Job No-	ART-730-04	Artwork Proof No.	P7	Non-Print Colours	Cutting Die			
MA No-	PL 46302/0132	Client Market	United Kingdom	Equate CMYK				
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Superseded Supplier Code	903042	3D Render ID	N.A.	Dimensions	184 x 310 mm	Min Te	ext Size used	9 pt
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Pregnancy and breast-feeding

Do not take Manevac 12 years plus if you are pregnant or breast-feeding

Driving and using machines

Manevac 12 Years Plus has no known effect on your ability to drive and use machines.

Important information for patients with an intolerance to some sugars Manevac 12 Years Plus 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 12 Years Plus

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 12 Years Plus exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure about taking Manevac 12 Years Plus.

Before taking this product, sit in an upright position. The granules should be taken using the measuring spoon included in the pack.

Manevac 12 Years Plus 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

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 12 Years Plus is two level measuring spoons (10g of granules).

You should not take Manevac 12 Years Plus for more than one week. Usually it is sufficient to take this medicinal product up to two to three times during that week.

Tell your doctor or pharmacist:

- If the symptoms worsen or persist while using Manevac 12 Years Plus
- There is no bowel movement within 3 days of use
- You need to take laxatives every day or if abdominal pain persists (See "Take special care with Manevac 12 Years Plus" in section 2.)

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

Use in children and adolescents

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

If you take more Manevac 12 Years Plus than you should

If you take too much Manevac 12 Years Plus 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 12 Years Plus or
- Take Manevac 12 Years Plus 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 12 Years Plus

If you forget to take your Manevac 12 Years Plus, 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

If you get any of the following side effects you should stop taking Manevac 12 Years Plus and go to the casualty department of your nearest hospital, 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
- nausea and vomiting
- 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 12 Years Plus.
- 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 12 Years Plus 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 12 Years Plus

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

Do not use Manevac 12 Years Plus 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 12 Years Plus 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 12 Years Plus looks like and contents of the pack

Manevac 12 Years Plus is presented as brown sugar-coated granules and is available in packs containing 250g of granules

Marketing Authorisation Holder

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

Manufacturer

Madaus GmbH

51101 Koeln Cologne

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

HFA Healthcare Limited Solihull, B91 1NF, UK

Tel: 0844 335 8270.

Manevac is a registered Trade Mark This leaflet was last revised in July 2023

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