



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:

1. What Manevac 12 Years Plus is and what it is used for
2. What you need to know before you take Manevac 12 Years Plus
3. How to take Manevac 12 Years Plus
4. Possible side effects
5. How to store Manevac 12 Years Plus
6. Contents of the pack and other information

1. 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 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 12 Years Plus)
- 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 further.

				Date: 21 JULY 2023		Time: 11:42	
Description	Manevac Granules, (2.60 g-0.11 g-0.34-0.66 g)/5 g, (2.60 g/0.11 g/0.34-0.66 g)/5 g, 250 g			No. of colours	1	Page Count	1 of 2
Component Type	Leaflet/IFU - Folded	Site Barcode/DataMatrix	400	Colours	Black		
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Superseded Affiliate Item Code	2482086	Vendor Job No.	N.A.	Equate CMYK with			
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MA No.	PL 46302/0132	Client Market	United Kingdom	Dimensions	184 x 310 mm	Min Text Size used	9 pt
Packing Site/Printer	Madaus GmbH (Troisdorf - DE)	Keyline/Drawing No.	WZ_013				
New Supplier Code	903240	Barcode Info	N.A.				
Superseded Supplier Code	903042	3D Render ID	N.A.				
Supplier SAP No.	N.A.						
Sign-offs							
V2 Oct 2022							

