|                | Holder of marketing authorisation:       | <b>USK</b> ®   | <b>1 capsule contains:</b><br>500 mg Plantago ovata, Forsk. (syn.P.ispaghula Roxb),<br>Seminis tegumentum (psyllium husks).<br>To be kept out of reach of children.<br>Can be used during pregnancy and when breastfeeding.<br>Read the patient information leaflet before use.  |
|----------------|--|--|--|
|                | W IS | I-HUSK CAPSULES  | Use:   |
| 5 707657 03003 | nehoej 34 · DK-2770 K                    | BAL MEDICINE<br>Ised for<br>VATED CHOLESTEROL LEVELS<br>STIPATION AND SLOW BOWEL<br>VABLE BOWEL SYNDROME (IBS)<br>RRHOEA | Herbal medicine for constipation and slow bowel movement. Herbal<br>medicine for non-bloody diarrhoea of short duration (2-3 days).<br>Herbal medicine when extra fibre intake is needed, for instance as<br>supplement when suffering from IBS, and when other causes have<br>been eliminated as cause of symptoms. Herbal medicine for<br>moderately elevated cholesterol (fat) in the blood, as a supplement<br>to diet. Treatment should be in consultation with a doctor.<br>Should not be used for children under 6 years of age without the<br>doctor's instructions.<br>MT no: 6104107 Batch no: |
| 5 <u>3</u>     | ਡ Non-prescription<br>ਦੂ medicine        | 225 capsules   | s Item no: 210289 Best before:   |

Information leaflet: Information for the user

HUSK Psyllium husks, hard capsules Plantago ovata Forsk.

- Please read this information leaflet carefully. It contains important information. HUSK is an herbal medicine. To obtain
- the best result you must follow the instructions for HUSK carefully.
- Safe the information leaflet. You may need to read it again.
- Contact your pharmacy, if you have any questions regarding the treatment.

- If you do not get better within 2-3 days, or you get worse, contact your doctor.
- Talk to the pharmacy or your doctor, if a side effect becomes worse, or you suffer from side effects not mentioned in this leaflet.

This leaflet contains information on:
1. Effect and usage
2. Information you should know before using HUSK
3. How to use HUSK
4. Side effects
5. Storage
6. Additional information

#### . EFFECT AND USAGE

HUSK contains vegetable fibres that retains water and thereby increases the volume of the intestinal content.

The increased intestinal content stimulates the natural contractions of the bowel.

# You can use HUSK:

with your doctor.

 when suffering from constipation and slow bowel movement. If there is no change in your condition within 3 days, contact your doctor.

- when suffering from non-bloody diarrhoea. If there is no change in your condition within 2-3 days, contact your doctor.
- if you need more fibres in your diet, i.e. if you are suffering from Irritable Bowel Syndrome (IBS). Before you take HUSK, your doctor must rule out any other cause of symptoms.
  when suffering from moderately elevated cholesterol (fat) levels in the blood. You must also be on a low fat diet. Treatment must be in consultation

If your doctor has prescribed HUSK for something else, you should always follow the doctor's instructions.

2. IMPORTANT INFORMATION YOU SHOULD KNOW BEFORE USING HUSK

#### Do not take HUSK:

• if you are hypersensitive (allergic) to the active substance or one of the other ingredients.

- if you suffer from intestinal volvulus.
   This manifests itself in
  - pains in stomach and intestines. If you are in pain or start getting pains, your doctor should examine you.
  - nausea and vomiting.
  - severe constipation.
- if you suffer from blockage of the gastrointestinal tract due to a tumour or inflammation.

- if you suffer from a acute gastrointestinal disease demanding operation, i.e. appendicitis.
- if you suffer from changes in the behaviour of your bowel function for more than two weeks.
- if you are bleeding from the rectum without any known cause.
- if you have difficulties swallowing.
- if you suffer from badly controlled diabetes mellitus.

# Be especially careful with the use of HUSK

Speak to your doctor if you:

- are suffering from inflammation of the bowel
   are experiencing difficulties
   When taking HUSK, you must always drink plenty of fluids (at least 50 ml to every 3 capsules), to avoid difficulties
- are experiencing difficulties every 3 capsules), to avoid difficulties swallowing. every 3 capsules, to avoid difficulties swallowing HUSK capsules or problems
- are suffering from disturbances in the bodily fluid and salt balance. diarrhoea

# • need to use a laxative every day for a longer period of time, so the doctor can examine the reason for the obstipation.

In some cases you may have to be especially careful taking HUSK. Talk to your doctor if you:

- suffer from reduced liver function.
- suffer from reduced kidney function.
- suffer from any other serious disease.

If you experience chest pains or start vomiting, you should immediately seek medical attention.

it is especially important that you drink plenty of fluids and have enough sugar and salt.

Treatment of weak or elderly patients demands supervision from medical personal.

If you are working with or have previously worked with Psyllium husk, you have a higher risk of experiencing allergic reactions.

#### Use of other medicines

You should always talk to your doctor or the pharmacist if you are taking medicine or have used it recently. This also applies to medicine that you can obtain without prescription, medicine bought abroad, other herbal medicines, strong vitamins and minerals as well as dietary supplements. Talk to your doctor if you are taking medicine:

 for low metabolism (levothyroxine).
 that slow down the intestinal movements and may cause constipation, e.g. medicine for strong pairs (e.g. merphine, kotchemiden)

pains (e.g. morphine, ketobemidon, oxycodon, codein) and medicine for diarrhoea (e.g. loperamide).

Psyllium husks reduce the transit time through the intestines and may affect the absorption of other medication. You must take HUSK at the latest 1-2 hours before/after you take any other medication.

This is especially important when taking:

 vitamins, e.g. cyanocobalamin (vitamin B<sub>12</sub>) for pernicious anaemia. minerals, e.g. lithium for depression.  heart medication (digoxin).
 blood diluting medication (warfarin, phenprocoumon).
 medication for epilepsy (carbamazepine).

If you suffer from insulin-dependent diabetes and are taking HUSK with your meal, you should be aware that it may be necessary for you to lower your insulin

dosage

Use of HUSK with food and beverages If you suffer from insulin-dependent diabetes and are taking HUSK with your meal, you should be aware that it may be necessary for you to lower your insulin

dosage. Apart from this there is no knowledge of any other problems in connection with taking HUSK with food and beverages. **Pregnancy and breastfeeding** Before taking any medicine, you should seek advice from the doctor or the pharmacy.

Pregnancy: You can take HUSK during pregnancy. Breastfeeding: You can take HUSK when

breastfeeding.

# Traffic and work safety

HUSK does not affect work safety or the ability to move around safely in traffic.

3. HOW TO USE HUSK

When suffering from constipation, diarrhoea or irritable bowel syndrome: Adults: 6-10 capsules, morning and night Children over 6 years of age: 3 capsules, morning and night When suffering from elevated cholesterol level in the blood: Adults: 10 capsules, morning and night

 Children: You may only use HUSK for children under 6 years of age after instructions by your doctor.

HUSK should always be taken with 1-2 glasses of fluid HUSK should not be taken immediately before bedtime.

If your doctor has prescribed another dosage, you should always follow the doctor's instructions.

## If you have taken too much HUSK

Contact the doctor, the emergency room or the pharmacy if you have taken more HUSK than specified in this leaflet and you are feeling unwell. Bring the packaging.

Symptoms of an overdose of HUSK are discomforts in the gastrointestinal tract, r especially constipation. This especially occurs if you drink insufficient fluids. Worst case scenario is a risk of intestinal volvulus.

# If you forgot to take HUSK

You must not take a double dosage in compensation for the forgotten dosage.

# 4. SIDE EFFECTS

Like any other medicine HUSK can have side effects.

#### Serious side effects:

Very rare side effects: Occurs in less than 1 out of 10,000 patients (less than 0.01 %):

Sudden skin rash, respiratory problems and fainting (within minutes to hours) due to allergic reactions (anaphylactic reaction). Can be life threatening.

Common side effects: Occurs in more than 1 and 10 out of 100 patients (1-10 %): Stomach aches.

Flatulence and feeling bloated.

Occurs in more than 1 out of 10 patients

Non serious side effects:

Very common side effects:

(more than 10 %):

Rare side effects:

Occurs in 1 and 10 out of 10,000 patients (less than 0.01-0.1 %): respiratory problems. Contact a doctor immediately or the emergency room. If necessary, dial 112. watery eyes, runny nose, hives, rash.

Rare side effects: Occurs in 1 and 10 out of 10,000 patients (less than 0.01-0.1 %): Inflammation of the eye with red and

Inform your doctor or the pharmacy if you experience side effects that persist or aets worse or vou experience side effects not mentioned in this leaflet.

Side effect not mentioned here, should be reported to the Danish Medicines Agency, so the knowledge of side effects can improve. You or your relatives can report the side effects yourselves directly to the Danish Medicines Agency, You will find a form and a guide on the Danish Medicines Agency's website www.meldenbivirkning.dk

5. STORAGE To be kept out of reach of children.

Do not use HUSK after the date of expiry Packing sizes: printed on the packaging. 225 pieces.

Always hand in remains of medicine to the pharmacy. Out of consideration to the environment you should not throw medicine remains in the drain, toilet or the rubbish bin.

6. ADDITIONAL INFORMATION

## HUSK contains:

1 HUSK Psyllium-husk capsule contains: 500 mg *Plantago ovata*, Forsk. (syn. P.ispaghula Roxb), seminis tegumentum (psyllium husks).

Appearance and packing sizes: Appearance: oblong clear hard capsules with a grevish powder.

Holder of marketing authorisation and manufacturer:

W. Ratje Froeskaller ApS Kirstinehoei 34 DK-2770 Kastrup tel. +45 32 51 96 00 info@husk.dk

This information leaflet was last approved: 12/2009