

August 2024

Please note that there are currently 2 leaflets available for the Ovex Suspension license [PL 15513/0313].

It is the same product licence number for both leaflets *i.e.*, PL 15513/0313.

The information contained within each leaflet is identical apart from the manufacturer details and leaflet dimensions.

The leaflets are differentiated by manufacturer and respective dimensions.

1. PIL 1 (pages 2-3) - 3 column format, dimensions 145x260 mm

Manufacturer: Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

or

2. PIL 2 (pages 4-5) - 3 column format, dimensions 140 x 295 mm

Manufacturer: Lusomedicamenta Sociedade Técnica Farmacêutica,S.A.,Estrada Consiglieri Pedroso 66, 69-B, 2730-055 Barcarena, Portugal

This is a combined pdf of both leaflets.

Both these PILs are from different manufacturers as mentioned above and it will be inserted in carton as per its manufactured site. For Beerse carton, Beerse PIL (PIL 1) will be inserted and for Lusomedicamenta site's carton, Lusomedicamenta PIL (PIL 2) will be inserted.

OVEX™

SUSPENSION

mebendazole

- This medicine is used to treat threadworm infections of the gut.
- This medicine is for use by adults and children aged over 2 years.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after a few days.

1 What the medicine is and what it is used for

Ovex Suspension is a medicine, which is used to treat threadworm (sometimes known as pinworm) infections of the gut. The medicine contains mebendazole, which is one of a group of medicines called 'anthelmintics'. This medicine is for use in adults and children aged over 2 years.

2 What you need to know before you take this medicine

This medicine is suitable for most adults and children, but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

X Do not use this medicine...

- If you have ever had a **bad reaction** to any of the ingredients.
- If it is for a **child under 2 years**.
- If you are **pregnant or think you are pregnant**.

If any of these apply to you, **get advice from a doctor or pharmacist without using Ovex Suspension.**

! Talk to your doctor or pharmacist...

- If you have been told by your doctor that you have an **intolerance to some sugars**.
- If you are taking any **other medicines**, including:
 - **Metronidazole** (a drug used to treat **bacterial and protozoan infections**) as a serious skin reaction can rarely occur.
 - **Cimetidine** (used to treat excess **stomach acidity**).

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

If any of the bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

! If you are pregnant or breast-feeding

Do not take this medicine if you are pregnant, or think you might be pregnant. Ask your doctor or pharmacist for advice before taking this medicine if you are breast-feeding.

! Special warnings about this medicine

Since threadworms can spread very easily, it is strongly recommended that all the family (except pregnant, breast-feeding women or children under 2 years) are treated at the same time and that suitable hygiene precautions are followed to prevent re-infection (see Section 7 of this leaflet for more advice).

! Some of the ingredients can cause problems

- This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.
- Methyl (E218) and propyl (E216) parahydroxybenzoate may cause allergic reactions which could possibly be delayed.

! Important information on some of the other ingredients in this medicine

- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml dose, that is to say essentially 'sodium-free'.
- This medicine contains 0.819 mg propylene glycol (E1520) in each 5 ml dose, which is equivalent to 0.1638 mg/ml.

3 How to take this medicine

Check the table below to see how much medicine to take.

- Always **shake the bottle** thoroughly before use.
- The suspension should be taken using the 5 ml measuring cup in the pack.
- For oral use only.
- Do not use more than the stated dose shown in the table.
- Always supervise a child if they are taking this medicine.

i Children under 2 years old

This medicine is not recommended for children aged under 2 years. It should be given to children aged 1-2 years only under medical supervision and if there are no suitable alternatives.

i Adults and children aged 2 years and over

Age	Dose
Adults and children aged 2 years and over. Take one 5 ml dose per family member.	
<ul style="list-style-type: none"> ■ You must talk to a doctor if you do not feel better or if you feel worse after a few days. ■ If you are re-infected your pharmacist may recommend that a second dose is taken after 2 weeks. 	
! If anyone takes too much	
If anyone has taken too much Ovex Suspension, contact a doctor or your nearest Accident & Emergency department (Casualty) taking this leaflet and pack with you.	
4 Possible side-effects	
Like all medicines, Ovex can cause side-effects, although not everybody gets them.	
If you experience any of the following, stop using the medicine and seek immediate medical help:	
Rare: (may affect up to 1 in 1,000 people)	
<ul style="list-style-type: none"> ■ Convulsions (seizures/fits). ■ Allergic reactions including unexplained wheezing, shortness of breath, sudden swelling of your face or throat, and hives (also known as 'nettle rash' or 'urticaria'). ■ Skin rashes (which may be severe and include blistering or peeling of the skin) and itching, and may be accompanied by a high temperature. 	
If you experience any of the following, stop using the medicine and talk to your doctor or pharmacist:	
Common: (may affect up to 1 in 10 people)	
<ul style="list-style-type: none"> ■ Stomach pain 	
Uncommon: (may affect up to 1 in 100 people)	
<ul style="list-style-type: none"> ■ Stomach discomfort ■ Diarrhoea ■ Wind 	





Other effects that may occur include:

Rare: (may affect up to 1 in 1,000 people)

- Inflammation of the liver or abnormal liver function
- Reduction in white blood cells (which reduces the body's defences against infection)
- Unusual hair loss
- Dizziness

Very rare: (may affect up to 1 in 10,000 people)

- Inflammation of the kidneys*
- Decrease in bone marrow* activity resulting in reduced production of blood cells
- Nausea
- Vomiting

*observed in higher and prolonged doses

Reporting of side-effects

If you experience any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the 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 this medicine

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

Do not use this medicine after the expiry date which is stated on the carton after 'Expiry'. The expiry date refers to the last day of that month.

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 protect the environment.

6 Contents of the pack and other information

What's in this medicine?

The active ingredient in Ovex Suspension is: Mebendazole 100 mg per 5 ml.

Other ingredients are: Sucrose, Microcrystalline cellulose and carmellose sodium, Methylcellulose, Methylparahydroxybenzoate (E218), Propylparahydroxybenzoate (E216), Sodium laurilsulfate, banana flavour, (containing propylene glycol (E1520)), citric acid monohydrate and purified water.

(For further information on some of the ingredients see Section 2).

What the medicine looks like

Ovex Suspension is a banana flavoured, white liquid available in 30 ml packs (6 single doses).

Product Licence holder:

McNeil Products Limited, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

Manufacturer:

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

This leaflet was last revised in January 2021.

Ovex is a registered trade mark.

7 Further advice regarding threadworms

What are threadworms?

Threadworms (*Enterobius vermicularis*) are tiny white parasitic worms that live in the bowel. They are approximately half an inch long and resemble threads of white cotton – hence the name threadworms.

How common are threadworms?

Threadworms are extremely common, especially in children. It is estimated that up to 40% of children under ten years in the UK may be affected at any one time. Once a child has threadworms, it is very easy for the rest of the family to get them.

How do they spread?

Threadworms spread by producing large numbers of tiny eggs. These eggs are so small that they cannot be seen with the naked eye. When swallowed, the eggs pass into the bowel where they hatch into worms. When mature, the female threadworm lays her eggs at night around the anal area, which causes an "itchy bottom". The resulting irritation can cause intense scratching, which may lead to further infections if the skin becomes sore or broken. Scratching also allows transfer of the eggs to the fingers and nails. Eggs can then be easily transferred to the mouth by finger sucking or nail biting, causing re-infection, and spread to other members of the family by direct contact or via food, towels and bed linen etc. Threadworm eggs are present in house dust; they stick to clothing, carpets, towels and bed linen; they can also be picked up on unwashed vegetables and salads. Because the eggs are so small and so widespread, it is very easy for them to be swallowed.

Lifecycle of threadworms

2 - 6 weeks.

1. Scratching the bottom transfers eggs to fingers and from there back to the mouth or to others either by direct contact or via food, bed linen etc.
2. Eggs swallowed.
3. Female worms migrate to the anal area to lay eggs at night.



Are they harmful?

Threadworms do not cause serious damage but they are an irritating problem. Besides the intense itching, which can be distressing and embarrassing for the sufferer, they can also lead to disturbed sleep, tummy aches, irritable crying, loss of appetite or an unusually large appetite. Sometimes, threadworms can be transferred to the vagina and urinary passage. This can result in vaginal irritation and discharge, symptoms of cystitis or bed wetting.

Who gets threadworms?

Anyone, although they are more common in children. It does not mean that your family or your home are not clean. Because threadworms are passed on very easily it is a wise precaution to treat everyone in the family at the same time.

How can you tell if someone has threadworms?

The most obvious sign of threadworms is intense itching in the anal area, especially at night, although this does not affect everyone. If your children frequently scratch their bottoms, suffer from disturbed sleep or become irritable, it is worth checking their motions and the anal area for tiny white threads. If one member of the family has threadworms, the rest of the family may already have picked up the infection, even if they do not have obvious symptoms.

Important note

Threadworms only affect humans, they do not affect pets.

General advice

To ensure that you and your family do not infect others or re-infect yourselves, you should also follow the hygiene measures listed below for at least six weeks:

- Keep nails short.
- Discourage nail biting or finger sucking.
- Wear pyjamas or underclothes in bed.
- In the mornings, wash thoroughly around the bottom.
- Provide a towel for the exclusive use of each member of the household.
- Change clothes regularly.
- Regularly wash and iron bed linen.
- Thoroughly wash hands and nails after using the toilet and before each meal.



Do you need to keep your children off school?

No. As long as the children are treated and the general hygiene measures outlined above are followed, there is no reason to keep them off school.

How can you stop the problem coming back?

Threadworms are easily treated but unless the following precautions are taken the problem may recur:

- Follow the general advice above.
- Make sure everyone in the family is treated at the same time.



GB - AW_180084

OVEX™

SUSPENSION

mebendazole

- This medicine is used to treat threadworm infections of the gut.
- This medicine is for use by adults and children aged over 2 years.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after a few days.

1 What the medicine is and what it is used for

Ovex Suspension is a medicine, which is used to treat threadworm (sometimes known as pinworm) infections of the gut. The medicine contains mebendazole, which is one of a group of medicines called 'anthelmintics'.

This medicine is for use in adults and children aged over 2 years.

2 What you need to know before you take this medicine

This medicine is suitable for most adults and children, but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

X Do not use this medicine...

- If you have ever had a **bad reaction** to any of the ingredients.
- If it is for a **child under 2 years**.
- If you are **pregnant or think you are pregnant**.

If any of these apply to you, **get advice from a doctor or pharmacist without using Ovex Suspension.**

! Talk to your doctor or pharmacist...

- If you have been told by your doctor that you have an **intolerance to some sugars**.
- If you are taking any **other medicines**, including:
 - **Metronidazole** (a drug used to treat **bacterial and protozoan infections**) as a serious skin reaction can rarely occur.
 - **Cimetidine** (used to treat excess **stomach acidity**).

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

If any of the bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

! If you are pregnant or breast-feeding

Do not take this medicine if you are pregnant, or think you might be pregnant. Ask your doctor or pharmacist for advice before taking this medicine if you are breast-feeding.

! Special warnings about this medicine

Since threadworms can spread very easily, it is strongly recommended that all the family (except pregnant, breast-feeding women or children under 2 years) are treated at the same time and that suitable hygiene precautions are followed to prevent re-infection (see Section 7 of this leaflet for more advice).

! Some of the ingredients can cause problems

- This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.
- Methyl (E218) and propyl (E216) parahydroxybenzoate may cause allergic reactions which could possibly be delayed.

! Important information on some of the other ingredients in this medicine

- This medicine contains less than 1 mmol sodium (23 mg) per 5 mL dose, that is to say essentially 'sodium-free'.
- This medicine contains 0.819 mg propylene glycol (E1520) in each 5 ml dose, which is equivalent to 0.1638 mg/ml.

3 How to take this medicine

Check the table below to see how much medicine to take.

- Always **shake the bottle** thoroughly before use.
- The suspension should be taken using the measuring cup provided in the pack.
- For oral use only.

- Do not use more than the stated dose shown in the table.
- Always supervise a child if they are taking this medicine.

i Children under 2 years old

This medicine is not recommended for children aged under 2 years. It should be given to children aged 1-2 years only under medical supervision and if there are no suitable alternatives.

i Adults and children aged 2 years and over

Age	Dose
Adults and children aged 2 years and over. Take one 5 ml dose per family member.	
<ul style="list-style-type: none"> ■ You must talk to a doctor if you do not feel better or if you feel worse after a few days. ■ If you are re-infected your pharmacist may recommend that a second dose is taken after 2 weeks. 	

! If anyone takes too much

If anyone has taken too much Ovex Suspension, contact a doctor or your nearest Accident & Emergency department (Casualty) taking this leaflet and pack with you.

4 Possible side-effects

Like all medicines, Ovex can cause side-effects, although not everybody gets them.

If you experience any of the following, stop using the medicine and seek immediate medical help:

- Rare:** (may affect up to 1 in 1,000 people)
- Convulsions (seizures/fits).
 - Allergic reactions including unexplained wheezing, shortness of breath, sudden swelling of your face or throat, and hives (also known as 'nettle rash' or 'urticaria').
 - Skin rashes (which may be severe and include blistering or peeling of the skin) and itching, and may be accompanied by a high temperature.

If you experience any of the following, stop using the medicine and talk to your doctor or pharmacist:

- Common:** (may affect up to 1 in 10 people)
- Stomach pain
- Uncommon:** (may affect up to 1 in 100 people)
- Stomach discomfort
 - Diarrhoea
 - Wind

Other effects that may occur include:

Rare: (may affect up to 1 in 1,000 people)

- Inflammation of the liver or abnormal liver function
- Reduction in white blood cells (which reduces the body's defences against infection)
- Unusual hair loss
- Dizziness

Very rare: (may affect up to 1 in 10,000 people)

- Inflammation of the kidneys*
- Decrease in bone marrow* activity resulting in reduced production of blood cells
- Nausea
- Vomiting

*observed in higher and prolonged doses

Reporting of side-effects

If you experience any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the 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 this medicine

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

Do not use this medicine after the expiry date which is stated on the carton after 'Expiry'. The expiry date refers to the last day of that month.

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 protect the environment.

6 Contents of the pack and other information

What's in this medicine?

The active ingredient in Ovex Suspension is: Mebendazole 100 mg per 5 ml.

Other ingredients are: Sucrose, Microcrystalline cellulose and carmellose sodium, Methylcellulose, Methylparahydroxybenzoate (E218), Propylparahydroxybenzoate (E216), Sodium laurilsulfate, banana flavour, (containing propylene glycol (E1520)), citric acid monohydrate and purified water.

(For further information on some of the ingredients see Section 2).

What the medicine looks like

Ovex Suspension is a banana flavoured, white liquid available in 30 ml packs with a dosing cup.

Product Licence holder:

McNeil Products Limited, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

Manufacturer:

Lusomedicamenta Sociedade Técnica Farmacêutica, S.A.,
Estrada Consiglieri Pedrosa 66, 69-B, 2730-055 Barcarena, Portugal

This leaflet was last revised in June 2024.

Ovex is a registered trade mark.

7 Further advice regarding threadworms

What are threadworms?

Threadworms (*Enterobius vermicularis*) are tiny white parasitic worms that live in the bowel. They are approximately half an inch long and resemble threads of white cotton – hence the name threadworms.

How common are threadworms?

Threadworms are extremely common, especially in children. It is estimated that up to 40% of children under ten years in the UK may be affected at any one time. Once a child has threadworms, it is very easy for the rest of the family to get them.

How do they spread?

Threadworms spread by producing large numbers of tiny eggs. These eggs are so small that they cannot be seen with the naked eye. When swallowed, the eggs pass into the bowel where they hatch into worms. When mature, the female threadworm lays her eggs at night around the anal area, which causes an "itchy bottom". The resulting irritation can cause intense scratching, which may lead to further infections if the skin becomes sore or broken. Scratching also allows transfer of the eggs to the fingers and nails. Eggs can then be easily transferred to the mouth by finger sucking or nail biting, causing re-infection, and spread to other members of the family by direct contact or via food, towels and bed linen etc. Threadworm eggs are present in house dust; they stick to clothing, carpets, towels and bed linen; they can also be picked up on unwashed vegetables and salads. Because the eggs are so small and so widespread, it is very easy for them to be swallowed.

Lifecycle of threadworms

2 - 6 weeks.

1. Scratching the bottom transfers eggs to fingers and from there back to the mouth or to others either by direct contact or via food, bed linen etc.
2. Eggs swallowed.
3. Female worms migrate to the anal area to lay eggs at night.

Are they harmful?

Threadworms do not cause serious damage but they are an irritating problem. Besides the intense itching, which can be distressing and embarrassing for the sufferer, they can also lead to disturbed sleep, tummy aches, irritable crying, loss of appetite or an unusually

large appetite. Sometimes, threadworms can be transferred to the vagina and urinary passage. This can result in vaginal irritation and discharge, symptoms of cystitis or bed wetting.

Who gets threadworms?

Anyone, although they are more common in children. It does not mean that your family or your home are not clean. Because threadworms are passed on very easily it is a wise precaution to treat everyone in the family at the same time.

How can you tell if someone has threadworms?

The most obvious sign of threadworms is intense itching in the anal area, especially at night, although this does not affect everyone. If your children frequently scratch their bottoms, suffer from disturbed sleep or become irritable, it is worth checking their motions and the anal area for tiny white threads. If one member of the family has threadworms, the rest of the family may already have picked up the infection, even if they do not have obvious symptoms.

Important note

Threadworms only affect humans, they do not affect pets.

General advice

To ensure that you and your family do not infect others or re-infect yourselves, you should also follow the hygiene measures listed below for at least six weeks:

- Keep nails short.
- Discourage nail biting or finger sucking.
- Wear pyjamas or underclothes in bed.
- In the mornings, wash thoroughly around the bottom.
- Provide a towel for the exclusive use of each member of the household.
- Change clothes regularly.
- Regularly wash and iron bed linen.
- Thoroughly wash hands and nails after using the toilet and before each meal.



Do you need to keep your children off school?

No. As long as the children are treated and the general hygiene measures outlined above are followed, there is no reason to keep them off school.

How can you stop the problem coming back?

Threadworms are easily treated but unless the following precautions are taken the problem may recur:

- Follow the general advice above.
- Make sure everyone in the family is treated at the same time.

