

**PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**  
**Flagyl®-S 200mg/5ml oral suspension**  
(metronidazole benzoate)

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

The name of your medicine is Flagyl-S 200mg/5ml oral suspension but will be referred to as Flagyl throughout this leaflet.

**What is in this leaflet:**

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

## 1. What Flagyl is and what it is used for

Flagyl contains a medicine called metronidazole benzoate. This belongs to a group of medicines called antibiotics.

It works by killing bacteria and parasites that cause infections in your body.

It can be used to:

- Treat infections of the blood, brain, lung, bones, genital tract, pelvic area, stomach and intestines
- Treat gum ulcers and other dental infections
- Treat infected leg ulcers and pressure sores
- Prevent infections after surgery

If you need any further information on your illness, speak to your doctor.

## 2. What you need to know before you take Flagyl

**Do not take Flagyl and tell your doctor if:**

- You are allergic (hypersensitive) to metronidazole, nitroimidazoles (e.g. tinidazole) or any of the other ingredients of this medicine (listed in Section 6:).  
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Do not take Flagyl if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Flagyl.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Flagyl if:

- You have or have ever had a liver problem.
- You are having kidney dialysis (see section 3: 'People having kidney dialysis')
- You have a disease of the nervous system

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking your medicine. Do this even if they have applied in the past.

Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with Flagyl.

If you are affected by Cockayne syndrome, your doctor should also monitor your liver function frequently while you are being treated with Flagyl and afterwards.

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP) have been reported with the use of Flagyl.

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of the mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localised on the skin folds, trunk and upper extremities

The highest risk for occurrence of serious skin reactions is within one week, typically, within 48 hours of treatment. If you develop a serious rash or another of these skin symptoms, stop taking Flagyl and contact your doctor or seek medical attention immediately.

Tell your doctor immediately and stop taking Flagyl if you develop:

- Stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic coloured stools or itching.

**Other medicines and Flagyl**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Flagyl can affect the way some other medicines work. Also, some other medicines can affect the way Flagyl works.

In particular tell your doctor if you are taking any of the following medicines:

- Medicines used to thin the blood such as warfarin
- Lithium for mental illness
- Phenobarbital or phenytoin for epilepsy
- 5 fluorouracil for cancer
- Busulfan for leukaemia (cancer of the blood cells)
- Ciclosporin – to prevent the rejection of organs after transplant
- Disulfiram for alcoholism

If you are not sure, talk to your doctor or pharmacist before taking Flagyl.

**Flagyl with food, drink and alcohol**

Do not drink any alcohol while you are taking Flagyl and for 48 hours after finishing your course. Drinking alcohol while using Flagyl might cause unpleasant side effects, such as feeling sick (nausea), being sick (vomiting), stomach pain, hot flushes, very fast or uneven heartbeat (palpitations) and headache.

**Pregnancy and breast-feeding**

Tell your doctor before using Flagyl if:

- You are pregnant, might become pregnant or think you may be pregnant. Flagyl should not be taken during pregnancy unless considered absolutely necessary.
- You are breast-feeding. It is better not to take Flagyl if you are breast-feeding. This is because small amounts may pass into the mother's milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

While taking Flagyl you may feel sleepy, dizzy, confused, see or hear things that are not there (hallucinations), have fits (convulsions) or temporary eyesight problems (such as blurred or double vision). If this happens, do not drive or use any machinery or tools.

**Tests**

Your doctor may wish to carry out some tests if you have been using this medicine for more than 10 days.

**Flagyl contains**

- **Sucrose:** This is a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine.
- **Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216):** These are preservatives that are added to Flagyl to make the medicine last longer. These can cause an allergic reaction in some people.
- **Alcohol:** Flagyl contains 0.8% alcohol (ethanol) by volume; this is equivalent to 32mg alcohol per 5ml dose. At high doses this could be harmful for those suffering from alcoholism, liver disease or epilepsy.

## 3. How to take Flagyl

**Taking your medicine**

Always take this medicine exactly as your doctor or pharmacist has told you. It is important to finish a full course of treatment. The length of a course will depend on your needs and the illness being treated. Check with your doctor or pharmacist if you are not sure.

- Take Flagyl Suspension by mouth
- The dose of Flagyl will depend on your needs and the illness being treated
- The length of your treatment will depend on the type of illness you have and how bad it is
- Your doctor or pharmacist may dilute your Flagyl Suspension. In this case the pharmacist's label on the packaging will tell you how exactly much to take and how often.

The usual dose for adults and children is given below:

**To treat certain bacterial infection**

**Adults and children over 10 years**

- Take 10ml (400mg) of Flagyl Suspension once every 8 hours

**Children and infants**

- Your doctor will work out how much your child should take depending on their weight
- Repeat the dose every 8 hours
- If your child is a baby under 8 weeks of age, your doctor will give them one daily dose or two separate doses 12 hourly

**To prevent infections from happening after surgery**

**Children**

- Give your child Flagyl suspension 2-3 hours before their operation
- Your doctor will work out how much your child should take depending on their weight

**Other types of infections**

For treatment of other infections caused by parasites and some bacteria your doctor will decide how much Flagyl you need to take. This will depend on your illness and how bad it is. The pharmacist's label on the packaging will tell you exactly how much Flagyl Suspension to take and how often.

**People having kidney dialysis**

Kidney dialysis removes Flagyl from your blood. If you are having kidney dialysis you must take this medicine after your dialysis treatment.

**People with liver problems**

Your doctor may tell you to take a lower dose or to use the medicine less often.

**If you take more Flagyl than you should**

If you take more Flagyl than you should, tell your doctor or go to your nearest hospital casualty department straight away. Take the carton and bottle with you. This is so the doctor knows what you have taken.

**If you forget to take Flagyl**

If you forget to take Flagyl, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on this use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop taking Flagyl and see a doctor or go to a hospital straight away if:**

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria)  
This may mean you are having an allergic reaction to Flagyl.
- A serious but very rare side effect is a brain disease (encephalopathy). Symptoms vary but you might get a fever, stiff neck, headache, see or hear things that aren't there. You might also have problems using your arms and legs, problems with speaking or feel confused.

- You develop skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis. These can appear as reddish target-like spots or circular patches often with central blisters on the trunk, skin peeling, ulcers of the mouth, throat, nose genitals and eyes and can be preceded by fever and flu-like symptoms. Stop using Flagyl if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.
- You develop a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Flagyl if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

**Talk to your doctor straight away if you notice the following side effects.**

- Yellowing of the skin and eyes. This could be due to a liver problem (jaundice).
- Unexpected infections, mouth ulcers, bruising, bleeding gums, or severe tiredness. This could be caused by a blood problem.
- Severe stomach pain which may reach through to your back (pancreatitis)

**Tell your doctor or pharmacist if you notice any of the following side effects:**

**Very rare (affects less than 1 in 10 000 people)**

- Fits (convulsions)
- Mental problems such as feeling confused and seeing or hearing things that are not there (hallucinations)
- Problems with your eyesight such as blurred or double vision
- Skin rash or flushing
- Headache
- Darkening of the urine
- Feeling sleepy or dizzy
- Pains in the muscles or joints
- Liver problems including life-threatening liver failure (hepatocellular liver injury)

**Not known (frequency cannot be estimated from the available data)**

- Numbness, tingling, pain, or a feeling of weakness, in the arms or legs
- Unpleasant taste in the mouth
- Furred tongue
- Feeling sick (nausea), being sick (vomiting), upset stomach, stomach pain or diarrhoea
- Loss of appetite
- Fever
- Feeling depressed
- Pain in your eyes (optic neuritis)
- A group of symptoms together including: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover the brain and spinal cord (meningitis)
- Hearing impairment/hearing loss
- Ringing in the ears (tinnitus)
- You get a rash or skin discolouration with or without raised areas which often reoccurs at the same location each time the drug is taken

**Reporting of side effects**

If you get 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](http://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 Flagyl

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Store in the original package in order to protect from light.
- Do not take the medicine after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.
- If the medicine becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

**What Flagyl contains**

The active ingredient in the Flagyl is metronidazole  
 Each 5ml suspension contains 200mg metronidazole (as metronidazole benzoate).  
 The other ingredients are: sodium dihydrogen phosphate, ethanol (0.8% v/v), methyl parahydroxybenzoate (preservative E218), propyl parahydroxybenzoate (preservative E216), sucrose, magnesium aluminium silicate, water, lemon flavor oil and orange oil.

**What Flagyl looks like and contents of the pack**

The suspension is white to cream coloured with a slight yellow tinge and an odour of oranges and lemons.  
 It is available in 100ml amber glass bottles with child resistant closure and a 5ml measuring spoon.

**Manufactured by:** Unither Liquid Manufacturing, 1-3 Allee De La Neste, Zone Industrielle D'en Sigal, Colomiers F-31770, France.

**Procured from within the EU and repackaged by the Product Licence holder:**  
 B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Flagyl®-S 200mg/5ml oral suspension; PL 18799/2894**

**POM**

Leaflet date: 19.04.2021

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**Blind or partially sighted?**

**Is this leaflet hard to see or read?**

**Call 0208 515 3763 to obtain the leaflet in a format suitable for you.**

**PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**  
**Metronidazole 200mg/5ml oral suspension**  
(metronidazole benzoate)

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- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

The name of your medicine is Metronidazole 200mg/5ml oral suspension but will be referred to as Metronidazole throughout this leaflet.

**What is in this leaflet:**

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

## 1. What Metronidazole is and what it is used for

Metronidazole contains a medicine called metronidazole benzoate. This belongs to a group of medicines called antibiotics.

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It can be used to:

- Treat infections of the blood, brain, lung, bones, genital tract, pelvic area, stomach and intestines
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- Prevent infections after surgery

If you need any further information on your illness, speak to your doctor.

## 2. What you need to know before you take Metronidazole

**Do not take Metronidazole and tell your doctor if:**

- You are allergic (hypersensitive) to metronidazole, nitroimidazoles (e.g. tinidazole) or any of the other ingredients of this medicine (listed in Section 6:).  
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Do not take Metronidazole if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Metronidazole.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Metronidazole if:

- You have or have ever had a liver problem.
- You are having kidney dialysis (see section 3: 'People having kidney dialysis')
- You have a disease of the nervous system

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking your medicine. Do this even if they have applied in the past.

Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with Metronidazole.

If you are affected by Cockayne syndrome, your doctor should also monitor your liver function frequently while you are being treated with Metronidazole and afterwards.

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP) have been reported with the use of Metronidazole.

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of the mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
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The highest risk for occurrence of serious skin reactions is within one week, typically, within 48 hours of treatment. If you develop a serious rash or another of these skin symptoms, stop taking Metronidazole and contact your doctor or seek medical attention immediately.

Tell your doctor immediately and stop taking Metronidazole if you develop:

- Stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic coloured stools or itching.

**Other medicines and Metronidazole**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Metronidazole can affect the way some other medicines work. Also, some other medicines can affect the way Metronidazole works.

In particular tell your doctor if you are taking any of the following medicines:

- Medicines used to thin the blood such as warfarin
- Lithium for mental illness
- Phenobarbital or phenytoin for epilepsy
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- Busulfan for leukaemia (cancer of the blood cells)
- Ciclosporin – to prevent the rejection of organs after transplant
- Disulfiram for alcoholism

If you are not sure, talk to your doctor or pharmacist before taking Metronidazole.

**Metronidazole with food, drink and alcohol**

Do not drink any alcohol while you are taking Metronidazole and for 48 hours after finishing your course. Drinking alcohol while using Metronidazole might cause unpleasant side effects, such as feeling sick (nausea), being sick (vomiting), stomach pain, hot flushes, very fast or uneven heartbeat (palpitations) and headache.

**Pregnancy and breast-feeding**

Tell your doctor before using Metronidazole if:

- You are pregnant, might become pregnant or think you may be pregnant. Metronidazole should not be taken during pregnancy unless considered absolutely necessary.
- You are breast-feeding. It is better not to take Metronidazole if you are breast-feeding. This is because small amounts may pass into the mother's milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

While taking Metronidazole you may feel sleepy, dizzy, confused, see or hear things that are not there (hallucinations), have fits (convulsions) or temporary eyesight problems (such as blurred or double vision). If this happens, do not drive or use any machinery or tools.

**Tests**

Your doctor may wish to carry out some tests if you have been using this medicine for more than 10 days.

**Metronidazole contains**

- **Sucrose:** This is a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine.
- **Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216):** These are preservatives that are added to Metronidazole to make the medicine last longer. These can cause an allergic reaction in some people.
- **Alcohol:** Metronidazole contains 0.8% alcohol (ethanol) by volume; this is equivalent to 32mg alcohol per 5ml dose. At high doses this could be harmful for those suffering from alcoholism, liver disease or epilepsy.

## 3. How to take Metronidazole

**Taking your medicine**

Always take this medicine exactly as your doctor or pharmacist has told you. It is important to finish a full course of treatment. The length of a course will depend on your needs and the illness being treated. Check with your doctor or pharmacist if you are not sure.

- Take Metronidazole Suspension by mouth
- The dose of Metronidazole will depend on your needs and the illness being treated
- The length of your treatment will depend on the type of illness you have and how bad it is
- Your doctor or pharmacist may dilute your Metronidazole Suspension. In this case the pharmacist's label on the packaging will tell you how exactly much to take and how often.

The usual dose for adults and children is given below:

**To treat certain bacterial infection**

**Adults and children over 10 years**

- Take 10ml (400mg) of Metronidazole Suspension once every 8 hours

**Children and infants**

- Your doctor will work out how much your child should take depending on their weight
- Repeat the dose every 8 hours
- If your child is a baby under 8 weeks of age, your doctor will give them one daily dose or two separate doses 12 hourly

**To prevent infections from happening after surgery**

**Children**

- Give your child Metronidazole suspension 2-3 hours before their operation
- Your doctor will work out how much your child should take depending on their weight

**Other types of infections**

For treatment of other infections caused by parasites and some bacteria your doctor will decide how much Metronidazole you need to take. This will depend on your illness and how bad it is. The pharmacist's label on the packaging will tell you exactly how much Metronidazole Suspension to take and how often.

**People having kidney dialysis**

Kidney dialysis removes Metronidazole from your blood. If you are having kidney dialysis you must take this medicine after your dialysis treatment.

**People with liver problems**

Your doctor may tell you to take a lower dose or to use the medicine less often.

**If you take more Metronidazole than you should**

If you take more Metronidazole than you should, tell your doctor or go to your nearest hospital casualty department straight away. Take the carton and bottle with you. This is so the doctor knows what you have taken.

**If you forget to take Metronidazole**

If you forget to take Metronidazole, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on this use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop taking Metronidazole and see a doctor or go to a hospital straight away if:**

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria)  
This may mean you are having an allergic reaction to Metronidazole.
- A serious but very rare side effect is a brain disease (encephalopathy). Symptoms vary but you might get a fever, stiff neck, headache, see or hear things that aren't there. You might also have problems using your arms and legs, problems with speaking or feel confused.

- You develop skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis. These can appear as reddish target-like spots or circular patches often with central blisters on the trunk, skin peeling, ulcers of the mouth, throat, nose genitals and eyes and can be preceded by fever and flu-like symptoms. Stop using Metronidazole if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.
- You develop a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Metronidazole if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

**Talk to your doctor straight away if you notice the following side effects.**

- Yellowing of the skin and eyes. This could be due to a liver problem (jaundice).
- Unexpected infections, mouth ulcers, bruising, bleeding gums, or severe tiredness. This could be caused by a blood problem.
- Severe stomach pain which may reach through to your back (pancreatitis)

**Tell your doctor or pharmacist if you notice any of the following side effects:**

**Very rare (affects less than 1 in 10 000 people)**

- Fits (convulsions)
- Mental problems such as feeling confused and seeing or hearing things that are not there (hallucinations)
- Problems with your eyesight such as blurred or double vision
- Skin rash or flushing
- Headache
- Darkening of the urine
- Feeling sleepy or dizzy
- Pains in the muscles or joints
- Liver problems including life-threatening liver failure (hepatocellular liver injury)

**Not known (frequency cannot be estimated from the available data)**

- Numbness, tingling, pain, or a feeling of weakness, in the arms or legs
- Unpleasant taste in the mouth
- Furred tongue
- Feeling sick (nausea), being sick (vomiting), upset stomach, stomach pain or diarrhoea
- Loss of appetite
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## 5. How to store Metronidazole

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Store in the original package in order to protect from light.
- Do not take the medicine after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.
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- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

**What Metronidazole contains**

The active ingredient in the Metronidazole is metronidazole  
Each 5ml suspension contains 200mg metronidazole (as metronidazole benzoate).  
The other ingredients are: sodium dihydrogen phosphate, ethanol (0.8% v/v), methyl parahydroxybenzoate (preservative E218), propyl parahydroxybenzoate (preservative E216), sucrose, magnesium aluminium silicate, water, lemon flavor oil and orange oil.

**What Metronidazole looks like and contents of the pack**

The suspension is white to cream coloured with a slight yellow tinge and an odour of oranges and lemons.  
It is available in 100ml amber glass bottles with child resistant closure and a 5ml measuring spoon.

**Manufactured by:** Unither Liquid Manufacturing, 1-3 Allee De La Neste, Zone Industrielle D'en Sigal, Colomiers F-31770, France.

**Procured from within the EU and repackaged by the Product Licence holder:**  
B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Metronidazole 200mg/5ml oral suspension; PL 18799/2894**

**POM**

Leaflet date: 19.04.2021

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