

Sativex®

Oromucosal Spray 10 mL

Nabiximols equivalent to Cannabis sativa L. extracts (delta-9-tetrahydrocannabinol and cannabidiol)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sativex.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Sativex against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again

What Sativex is used for

Sativex is used to improve symptoms related to muscle stiffness (spasticity) in multiple sclerosis (MS). Health professionals sometimes talk about 'spasticity' when describing the muscle stiffness that you may experience. Spasticity means there is an increase in 'muscle tone'. In other words, when the muscle is moved, there is more resistance to this

movement than there normally would be. Muscles feel more rigid.

Sativex is used when other medicines have not worked to relieve your muscle stiffness.

Sativex is a mouth spray (oromucosal spray) which contains the active ingredient nabiximols which consists of cannabis extracts called cannabinoids.

Your doctor may prescribe Sativex for another purpose.

Ask your doctor if you have any questions about why Sativex has been prescribed for you.

This medicine is only available with a doctor's prescription.

Dependence on Sativex is unlikely.

Before you use Sativex

When you must not use it

Do not use Sativex if:

- You are allergic (hypersensitive) to cannabis extracts or any of the other ingredients of Sativex (listed in Section 6).
Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- You or anyone directly related to you has any mental health problems such as schizophrenia, psychosis or other significant psychiatric disorder. This does

not include depression due to your multiple sclerosis.

- You are breast-feeding.
- Do not use Sativex during pregnancy, unless advised to by your doctor.
- Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are pregnant or breast-feeding always ask your doctor for advice before taking any medicine.

Do not use this medicine if any of the above applies to you.

If you are not sure whether you should start using Sativex, talk to your doctor.

Before you start to use it

Tell your doctor if:

- You are pregnant or plan to become pregnant.
- You are under 18 years of age.
- You have epilepsy or regular fits (seizures).
- You have liver or kidney problems.
- You have a serious heart problem such as angina, a previous heart attack, poorly controlled high blood pressure or a problem with your heart rate or heart beat.
- You are elderly, especially if you have problems doing everyday activities such as making hot food and drinks.
- You have previously abused any drug or substance.

If you have not told your doctor about any of the above, tell them before you start using Sativex.

Important information about some of the ingredients of Sativex

- Sativex contains a small amount of ethanol (alcohol). The amount of alcohol in the maximum daily dose for most people (12 sprays) is equal to about one teaspoon of wine. This should normally be an insignificant amount but you may need to take this into account if you have to avoid alcohol completely.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Sativex.

Some medicines may interfere with Sativex. These include:

- Medicines to relax your muscles such as baclofen or diazepam. This is because taking Sativex with these medicines may increase the risk of you falling over.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Sativex.

If you see a different doctor or go into hospital, let them know all the medicines you are using.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Sativex.

How to use Sativex

Always use Sativex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Only use Sativex in your mouth – on the inside of your cheek or under your tongue.

You can use Sativex with or without food.

Your 4 week trial of Sativex

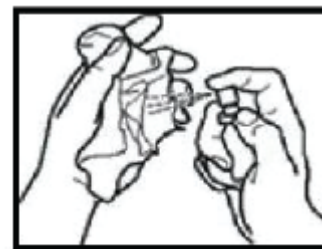
Only a specialist physician can start you on treatment with Sativex. The specialist will assess you from time to time to see if you should carry on taking it.

- Before you start using Sativex your specialist doctor will conduct a thorough assessment of how bad your spasticity is and how it has responded to other treatments.
- You will then have a 4 week trial of Sativex after which your specialist will do another assessment to see whether Sativex is helping you.
- Only if you have shown a significant improvement in your spasticity related symptoms after these 4 weeks should you continue to be treated with Sativex.

Your doctor will assess you from time to time to see if you should carry on taking it.

Opening your spray and getting it ready to use

1. Take your spray out of the refrigerator (see 'Storage' for important information on storing Sativex).
2. Write the date that you open your spray on the sticker provided in the box. Stick the sticker on the spray so that you can check the date. Do not use the spray after it has been open for more than 6 weeks (42 days).
3. Shake the spray container gently before use.
4. Remove the protective cap.
5. Hold the spray between your thumb and second finger. Put your first finger on the nozzle.
6. Holding it upright, practice spraying into a tissue 2 or 3 times until a fine spray appears. These sprays prime the pump and ensure it is working properly.
7. The spray is now ready to use. You will not need to do any more priming sprays until you open a new spray container.



Using your spray

1. Hold the spray between your thumb and second finger. Put your first finger on the nozzle.
2. Hold it upright and point into your mouth. Point the nozzle under your tongue or onto the inside of your cheek. Change the area in your mouth where you spray each time. This helps to stop any discomfort in one place.
3. Press the nozzle down firmly. Do not take more than one spray at a time, even if you feel that you only got a small amount of spray.
4. Replace the protective cap.



If you get spray in your eyes by accident, wash them as soon as possible with water.

- **Do not breathe in the spray.**
- **Do not spray near children or pets.**
- **Do not use the spray near naked flames or heat sources.**

How much to use

Working out how much to use

The number of sprays you need each day depends on you as an individual. Each person needs a different number of sprays to give them the best relief from their muscle stiffness, with the fewest unwanted effects.

When you first start using Sativex, you need to follow the days and

times in the table below until you find the best number of sprays for you.

Stop increasing your sprays when you find the best number of sprays for you.

This may only take a few days or it may take up to 2 weeks. Aim to use this number of sprays each day. You can then spread your sprays evenly over the whole day.

- Always leave at least 15 minutes between sprays.
- Do not over-exert yourself during the first couple of days of using Sativex until you know how it affects you.
- If you start to feel unwanted effects (usually dizziness) use one less spray each day until you find the best symptom relief with the fewest unwanted effects.
- When you find the best number of sprays for you, aim to use this number each day. You can then spread your sprays out evenly over the whole day, in a way that suits you. Still leave at least 15 minutes between sprays.

Knowing if your spray is nearly empty

After the 3 priming sprays, your spray contains up to 90 measured sprays (10 mL). When the spray is becoming empty, the noise of the spray action may change. You may also find the spray feels different in your mouth. This is because your spray is nearly empty. When this happens you should open a new spray container.

How long to use it

Continue to use this medicine for as long as your doctor tells you to.

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

If you forget to use it

If you forget a dose, use a spray as soon as you remember or when you feel you need a spray.

Do not use 2 sprays at the same time to make up for a missed spray.

If you have trouble remembering when to use your medicine, ask your pharmacist for hints.

If you use too much (overdose)

Australian patients:

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Sativex.

New Zealand patients:

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Sativex.

Day	Number of sprays		
	Morning sprays (between waking-up and 12 noon)	Evening sprays (between 4 pm and bedtime)	Total sprays each day
Day 1	0	1	1
Day 2	0	1	1
Day 3	0	2	2
Day 4	0	2	2
Day 5	1	2	3
Day 6	1	3	4
Day 7	1	4	5
Day 8	2	4	6
Day 9	2	5	7
Day 10	3	5	8
Day 11	3	6	9
Day 12	4	6	10
Day 13	4	7	11
Day 14	5	7	12

If you need more relief from your muscle stiffness after Day 10, continue to add one spray each day either in the morning or evening. For example, on Day 11 you would use nine sprays and on Day 12 you would use ten sprays.
You should not use more than 12 sprays in one day

Do this even if there are no signs of discomfort or poisoning.

If you accidentally use more of this medicine than you normally do you may:

- See or hear things that are not there (hallucinations).
- Feel dizzy, sleepy or confused.
- Feel your heart rate change.

If you get any of the above and they get serious, please tell your doctor or pharmacist.

While you are using Sativex

Things you must do

- If you are about to be started on any new medicine tell your doctor that you are taking Sativex.
- **Take special care if you drink alcohol while using Sativex.** Using Sativex and alcohol together may increase their effects (such as loss of balance or ability to respond quickly). If you drink alcohol with Sativex, see what effect it has on you. You can then decide how much alcohol you can drink.
- Talk to your doctor before using this medicine if you are pregnant or plan to become pregnant.
- Whether male or female you must use a reliable contraceptive method while using this medicine. Keep doing this for at least 3 months after your treatment has stopped.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

Things you must not do

- Do not give Sativex to anyone else, this medicine is for you. Even if they have the same condition as you, do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- Do not use Sativex while breast-feeding / do not use Sativex during pregnancy, unless advised to by your doctor.

Things to be careful of

Using Sativex with food and drink

- Take special care if you drink alcohol while using Sativex. Using Sativex and alcohol together may increase their effects (such as loss of balance or ability to respond quickly). If you drink alcohol with Sativex, see what effect it has on you. You can then decide how much alcohol you can drink.
- You can use Sativex with or without food.

Driving and using machines

- You must not drive or use machinery when you first start to take Sativex and until you are established on a stable daily dose.
- Sativex may cause you to feel sleepy or dizzy, which may impair your judgment and performance of skilled tasks. It has also rarely been reported to cause a brief loss of consciousness.
- Once you are more used to taking Sativex and your dose is stable, you should still not drive or use machinery if Sativex causes effects such as sleepiness or dizziness that could impair your ability to perform these tasks. If you are not sure, do not drive or operate machines.

Foreign travel with Sativex

- Check that it is legal for you to take this medicine into any countries you are travelling to and countries you are travelling through. Sativex is a Controlled Drug and its legal status will vary between countries.
- Driving while taking Sativex might be illegal in some countries.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Sativex.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

You are more likely to get side effects when you start your treatment. They are usually mild and wear off within a few hours.

If you get any of the following side effects, use less sprays or stop using Sativex until you feel normal again.

When you start using the medicine again, go back to the number of sprays where you did not feel these unwanted effects.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor if you notice any of the following side effects and they worry you

Very Common (affecting more than 1 in 10 people)

- feeling dizzy or tired

Common (affecting less than 1 in 10 people)

- lack of energy or feeling weak or generally unwell
- problems with your memory or having trouble concentrating
- feeling abnormal or drunk
- feeling sleepy or drowsy
- blurred vision
- constipation or diarrhoea
- feeling or being sick
- loss of balance or falling over
- changed sense of taste or a dry mouth
- mouth problems, including burning, pain or mouth ulcers

Uncommon (affecting less than 1 in 100 people)

- tummy pain
- sore throat or throat irritation
- mouth or teeth changing colour

- irritation where Sativex is sprayed
- red and swollen mouth or peeling inside it. Do not keep spraying onto these areas.

Tell your doctor as soon as possible if you notice any of the following:

Common (affecting less than 1 in 10 people)

- feeling depressed or disorientated
- feeling over-excited or losing touch with reality
- difficulty speaking
- eating more or less than usual
- seeing or hearing things that are not there (hallucinations)

Uncommon (affecting less than 1 in 100 people)

- believing ideas that are not true
- feeling that other people are against you
- fast or irregular heart beats, also called palpitations
- fainting.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- thoughts of suicide
- you develop signs of allergy such as swelling of the face, lips, tongue or other part of the body; severe dizziness or fainting; redness, itching or rash on the skin.

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects may only be found when your doctor does tests from time to time.

After using Sativex

Storage

- Do not use Sativex after the expiry date shown on the product packaging. The expiry date refers to the last day of that month.

- Store unopened Sativex upright in its carton in a refrigerator (2°C to 8°C). If it is not stored in a refrigerator it will become unstable and is unlikely to work.
- Store opened Sativex in an upright position below 25°C. Keep away from heat and direct sunlight.
- Do not use Sativex after it has been open for 42 days (10 mL).
- Unless your doctor tells you to, do not keep medicines that you no longer need.

Keep out of the reach and sight of children.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Medicines should not be disposed of via wastewater or household waste. Any unused medicine or medicine past its expiry date, as shown on the dispensing label or packaging, should be returned to the pharmacy.

Product description

What it looks like

Sativex is provided as a liquid in an amber 10 mL glass spray container with a brown plastic coating and a pump. The pump is protected with a plastic cap.

The number of measured sprays in the container is up to 90 sprays (after 3 priming sprays) for the 10 mL container.

Sativex is packed as single, 2, 3, 4, 6, 10 or 12 spray containers in each carton.

- delete as appropriate for Marketing

Ingredients

Active ingredients:

The active substances are cannabis extracts. Each millilitre (mL) contains 80mg nabiximols equivalent to 38-44 mg and 35-42 mg of two

extracts (as soft extracts) from *Cannabis sativa L.*, leaf and flower, corresponding to 27 mg/mL delta-9-tetra-hydrocannabinol (THC) and 25 mg/mL cannabidiol (CBD). Each 100 microlitre spray contains 2.7 mg THC and 2.5 mg CBD.

Inactive ingredients:

The other ingredients are ethanol, propylene glycol and peppermint oil.

Sponsor Details

Sativex® is supplied in Australia by:

Emerge Health Pty Ltd
Suite 3, Level 1, 2 Theatre Place
Canterbury, VIC 3126

Australian Register Number: AUST R 181978

Sativex® is supplied in New Zealand by:

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