

## **Sativex®**

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

**Oromucosal Spray 5.5 / 10 ml**

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### **What is in this leaflet**

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Please read all of this leaflet carefully before you start using Sativex.

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. 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 using this medicine, ask your doctor or pharmacist.**

Keep this leaflet with the medicine. You may need to read it again.

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### **What Sativex is used for**

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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.

### **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 may have prescribed Sativex for another reason.

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

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

The abrupt withdrawal of long-term Sativex treatment has not resulted in a consistent pattern or time-profile of withdrawal-type symptoms and the likely consequence will be limited to transient disturbances of sleep, emotion or appetite in some patients. No increase in daily dosage has been observed in long-term use, and patient self-reported levels of 'intoxication' are low. For these reasons, dependence on Sativex is unlikely.

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## **Before you use Sativex**

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### ***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).
- 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.

**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.

### ***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.

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## How to use Sativex

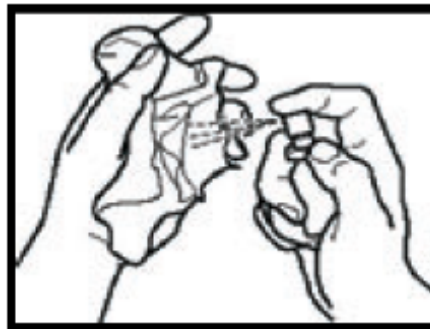
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Always use Sativex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

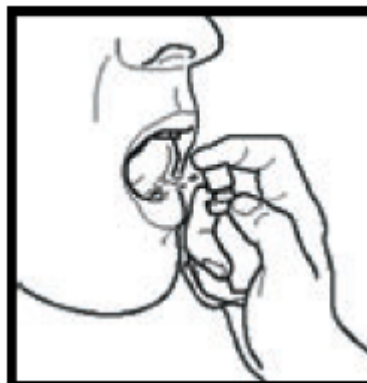
### Opening your spray and getting it ready to use

1. Take your spray out of the refrigerator.
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 4 weeks (28 days) for the 5.5 ml container or 6 weeks (42 days) for the 10 ml container.
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.

### Knowing if your spray is nearly empty

After the 3 priming sprays, your spray contains up to 48 measured sprays (5.5 ml) or 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 much to take

#### 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 included table 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.

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, unless your doctor tells you to.**

***How long to take it***

Your doctor will tell you how long you should use Sativex. If for any reason you decide to stop using Sativex, you should let your doctor know. If you stop taking your medicine suddenly, your sleep, appetite or feelings might be affected for a short time. Your muscle stiffness usually comes back gradually if you stop using Sativex.

***If you forget to take 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.

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**While you are using Sativex**

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***Things you must do***

- If you are about to be started on any new medicine tell your doctor that you are taking Sativex.
- 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.

### **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.

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### **In case of overdose**

#### ***If you take too much (overdose)***

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.

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.

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### **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 adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Possible side effects for Sativex are listed below. These are more likely 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.

#### **Very common (affecting more than 1 in 10 people)**

- Feeling dizzy or tired.

#### **Common (affecting less than 1 in 10 people)**

- Feeling depressed or confused.
- Feeling over-excited or losing touch with reality.
- Problems with your memory or having trouble concentrating.
- Feeling sleepy or giddy.

- Blurred vision.
- Difficulty speaking.
- Eating more or less than usual.
- Changed sense of taste or a dry mouth.
- Constipation or diarrhoea.
- Feeling or being sick.
- Mouth problems, including burning, pain or mouth ulcers.
- Lack of energy or feeling weak or generally unwell.
- Feeling abnormal or drunk.
- Loss of balance or falling over.

**Uncommon (affecting less than 1 in 100 people)**

- Seeing or hearing things that are not there (hallucinations).
- Believing ideas that are not true.
- Feeling that other people are against you.
- Thoughts of suicide.
- Fainting.
- Changes in pulse rate, heart rate or blood pressure.
- Sore throat or throat irritation.
- Tummy pain.
- 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.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

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**After using Sativex**

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***Storage***

- Keep out of the reach and sight of children.
- 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 28 days (5.5 ml) or 42 days (10 ml).
- Unless your doctor tells you to, do not keep medicines that you no longer need.

***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.

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**Product description**

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***What it looks like***

Sativex is provided as a liquid in a 5.5 ml or 10 ml glass spray container with a pump. The pump is protected with a plastic cap.

The number of measured sprays in the container is up to 48 sprays (after 3 priming sprays) for the 5.5 ml container or 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. Not all pack sizes may be marketed.

### ***Ingredients***

#### Active ingredients:

The active substances are cannabis extracts. Each millilitre (ml) contains 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.

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### **Sponsor Details**

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Sativex® is supplied in New Zealand by:  
Novartis New Zealand Limited  
Private Bag 65904  
Mairangi Bay  
Auckland 0754  
Building G, 5 Orbit Drive  
Rosedale  
Auckland 0632

Telephone 0800 652 422

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### **Date of Preparation**

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This leaflet was prepared on 18 April 2011.