SATIVEX®

Consumer Medicine Information (CMI) summary

The full CMI has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SATIVEX?

SATIVEX is a mouth spray (oromucosal spray) which contains the active ingredient nabiximols which consists of cannabis extracts called cannabinoids. SATIVEX is used to improve symptoms related to muscle stiffness (spasticity) in multiple sclerosis (MS). For more information, see Section 1. Why am I using SATIVEX? in the full CMI.

2. What should I know before I use SATIVEX?

Do not use if you have ever had an allergic reaction to nabiximols, cannabis extracts, or any of the ingredients listed at the end of the CMI, you or anyone directly related to you has any mental health problems such as schizophrenia, psychosis or other significant psychiatric disorder, or you are breastfeeding. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section 2. What should I know before I use SATIVEX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SATIVEX and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use SATIVEX?

- The number of sprays you need each day depends on you as an individual.
- Only use SATIVEX in your mouth – on the inside of your cheek or under your tongue.

More instructions can be found in Section 4. How do I use SATIVEX? in the full CMI.

5. What should I know while using SATIVEX?

Things you should do	• Remind any doctor (or healthcare professional who is prescribing a new medication for you), dentist, or pharmacist that you visit that you are using SATIVEX.
Things you should 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
Driving or using machines	• Australia: You must not drive or use machinery when you are taking SATIVEX. • New Zealand: You must not drive or use machinery when you first start to take SATIVEX and until you are established on a stable daily dose.
Drinking alcohol	• Take special care if you drink alcohol while using SATIVEX.
Looking after your medicine	• Store unopened SATIVEX upright in its carton in a refrigerator (2°C to 8°C). Store opened SATIVEX in an upright position below 25°C. Keep away from heat and direct sunlight.

For more information, see Section 5. What should I know while using SATIVEX? in the full CMI.

6. Are there any side effects?

Side effects include: feeling dizzy or tired, lack of energy, feeling weak or generally unwell, problems with memory/trouble concentrating, feeling abnormal/drunk, feeling sleepy/drowsy, blurred vision, constipation or diarrhoea, tummy pain, feeling or being sick, loss of balance or falling over, mouth problems (including changed sense of taste, dry mouth, burning, pain or mouth ulcers), sore throat or throat irritation, feeling depressed/disorientated, feeling over-excited/losing touch with reality, difficulty speaking, eating more/less than usual, seeing or hearing things that are not there (hallucinations). Serious side effects include thoughts of suicide, and signs of allergy such as swelling of the face, lips, tongue or other parts of the body; severe dizziness/fainting; redness, itching/rash on the skin.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

SATIVEX®

Active ingredient(s): *Cannabis sativa L. extracts (delta-9-tetrahydrocannabinol and cannabidiol)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SATIVEX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SATIVEX.**

Where to find information in this leaflet:

1. Why am I using SATIVEX?
2. What should I know before I use SATIVEX?
3. What if I am taking other medicines?
4. How do I use SATIVEX?
5. What should I know while using SATIVEX?
6. Are there any side effects?
7. Product details

1. Why am I using SATIVEX?

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

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 doctor may prescribe SATIVEX for another purpose.

Dependence on SATIVEX is unlikely.

2. What should I know before I use SATIVEX?

Warnings

Do not use SATIVEX if:

- you are allergic (hypersensitive) to cannabis extracts, or any of the ingredients listed at the end of this leaflet.
    - 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.

  Always check the ingredients to make sure you can use this medicine.
- 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.

Check with your doctor if you:

- are under 18 years of age
- have any other medical conditions, including
    - epilepsy or regular fits (seizures)
    - liver or kidney problems
    - 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
- take any medicines for any other condition
- are elderly, especially if you have problems doing everyday activities such as making hot food and drinks
- have previously abused any drug or substance

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not use SATIVEX during pregnancy, unless advised to by your doctor.

Check with your doctor if you are pregnant or intend to become pregnant.

Do not use SATIVEX if you are breast-feeding.

Fertility & Family planning

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.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with SATIVEX and affect how it works. 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 you see a different doctor or go into hospital, let them know all the medicines you are using.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SATIVEX.

4. How do I use SATIVEX?

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.

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 "Number of sprays" 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.

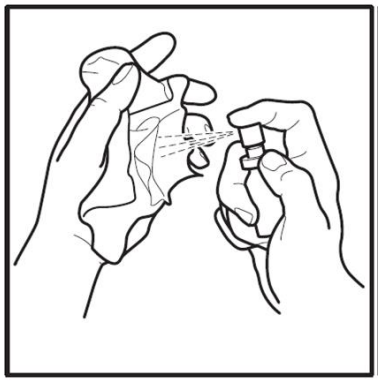
- Always leave at least 15 minutes between sprays.
- Do not over-exert yourself during the first couple of days of using SATIVEX until you know how it affects you.
- If you start to feel unwanted effects (usually dizziness) use one less spray each day until you find the best symptom relief with the fewest 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.

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

- Follow the instructions provided and use SATIVEX until your doctor tells you to stop. You should check with your doctor or pharmacist if you are not sure.

Opening your spray and getting it ready to use

1. Take your spray out of the refrigerator (see 'Looking after your medicine' 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.**

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 SATIVEX

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 SATIVEX

Australian patients:

If you think that you or anyone else may have used too much SATIVEX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

New Zealand patients:

If you think that you or anyone else may have used too much SATIVEX, you may need urgent medical attention.

You should immediately:

- phone the National Poisons Centre (**by calling 0800 POISON or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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.

5. What should I know while using SATIVEX?

Things you should 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.

Remind any doctor (or healthcare professional who is prescribing a new medication for you), dentist, or pharmacist that you visit that you are using SATIVEX.

Things you should 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.

Driving or using machines

Australia:

- You must not drive or use machinery when you are taking SATIVEX.
- SATIVEX may cause you to feel sleepy or dizzy, which may impair your judgment and performance of skilled tasks.

New Zealand:

- 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.

Drinking alcohol

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.

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.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

Medicines should not be disposed of via wastewater or household waste. If you no longer need to use this medicine or it is out of date, as shown on the dispensing label or packaging, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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. See the list of side effects and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General disorders and administration site conditions: • feeling dizzy or tired • lack of energy or feeling weak or generally unwell • feeling abnormal or drunk • feeling sleepy or drowsy • feeling or being sick • irritation where SATIVEX is sprayed **Nervous system or psychiatric disorders:** • problems with your memory or having trouble concentrating • loss of balance or falling over **Eye disorders:** • blurred vision **Gastrointestinal disorders:** • constipation or diarrhoea • tummy pain **Mouth and throat disorders:** • changed sense of taste or a dry mouth • mouth problems, including burning, pain or mouth ulcers • sore throat or throat irritation • mouth or teeth changing colour • red and swollen mouth or peeling inside it. Do not keep spraying onto these areas	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
General disorders and administration site conditions: • fainting **Nervous system or psychiatric disorders:** • feeling depressed or disorientated • feeling over-excited or losing touch with reality • difficulty speaking • seeing or hearing things that are not there (hallucinations) • believing ideas that are not true • feeling that other people are against you **Gastrointestinal disorders:** • eating more or less than usual **Cardiac disorders:** • fast or irregular heart beats, also called palpitations	**Tell your doctor as soon as possible if you notice any of these serious side effects.**

Very serious side effects

Serious side effects	What to do
Nervous system or psychiatric disorders: • thoughts of suicide **Immune system disorders:** • 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	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be 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.

Reporting side effects

Australia:

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

New Zealand:

After you have received medical advice for any side effects you experience, you can report side effects to consumer reporting at

https://pophealth.my.site.com/carmreportnz/s/. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What SATIVEX contains

Active ingredient (main ingredient)	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.
Other ingredients (inactive ingredients)	ethanol absolute propylene glycol peppermint oil

Do not take this medicine if you are allergic to any of these ingredients.

What SATIVEX looks like

SATIVEX is provided as a liquid in an amber 10 mL glass spray container with a brown plastic coating and a pump (Australia: AUST R 181978, New Zealand: TT50-8053). 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).

SATIVEX is packed as 3 spray containers in each carton.

Who distributes SATIVEX

SATIVEX is supplied in Australia by:

Jazz Pharmaceuticals ANZ

Suite 214, Level 2

165 Phillip Street

Sydney, NSW, 2000

Australia

Phone: 1800 577 422

SATIVEX is supplied in New Zealand by:

Pharmacy Retailing (NZ) Limited trading as Healthcare Logistics

58 Richard Pearse Drive

Airport Oaks

Mangere

Auckland 2022

New Zealand

This leaflet was prepared in July 2025.