

PACKAGE LEAFLET: INFORMATION FOR THE USER
NABILONE 0.25 MG & 1 MG CAPSULES

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 any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Nabilone is and what it is used for

The name of your medicine is Nabilone 0.25mg or 1mg Capsules (called Nabilone throughout this leaflet). Nabilone is a medicine that helps to reduce nausea and vomiting caused by many anticancer medicines. Nabilone is often used when other medicines have not helped your nausea or vomiting.

Nabilone is a man-made chemical known as a cannabinoid. It is not made from the Cannabis plant but it is similar to some marijuana extracts and can cause similar effects.

2. What you need to know before you take Nabilone

Do not take Nabilone

- If you are allergic (hypersensitive) to cannabinoids or any of the other ingredients of Nabilone (listed in section 6).
- If your nausea/vomiting is not due to anticancer treatment.
- If you are under 18 years. Nabilone is not meant for children.

Warnings and precautions

It is best if you take Nabilone in hospital, as you may experience side effects (see section 3).

Please talk to your doctor or pharmacist before taking Nabilone.

Caution is required when taking Nabilone

- in case of liver impairment. Use is not recommended in cases of severe liver impairments (see also section 3).
- in cases of kidney impairment.
- in patients with a history of drug, pharmaceutical, or alcohol abuse or alcohol dependence. Nabilone should not be taken with alcohol, sedatives, hypnotics, or other psychoactive substances, as these substances can increase the effect of Nabilone on the brain.
- in elderly patients and patients with high blood pressure or any other heart problems.
- in mental illness (including manic-depressive illness and depression). If you suffer from a mental illness, you should not use Nabilone.
- in children and adolescents under 18 years of age. Use is not recommended (see also section 3).

Patients should be closely monitored during inpatient hospitalization, as serious reactions can occur. Mood changes and other behavioural disturbances may occur. The effects may last for a variable and unpredictable period of time. Adverse psychiatric reactions may occur for 48 to 72 hours after treatment discontinuation.

The use of the drug Nabilone can lead to positive results in doping tests.

Other medicines and Nabilone

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor if you are taking any sleeping pills, painkillers or tranquillisers.

Nabilone should not be taken together with diazepam, sodium secobarbital, or codeine, as the CNS-inhibiting effects of these drugs may be increased.

Interactions with the following substances have been observed when cannabinoids are administered concomitantly:

- Amphetamines, cocaine, other sympathomimetics
- Atropine, scopolamine, antihistamines, other anticholinergics
- Amitriptyline, amoxapine, desipramine, other tricyclic antidepressants
- Barbiturates, benzodiazepines, lithium, opioids, buspirone, muscle relaxants, CNS-inhibiting substances
- Disulfiram
- Fluoxetine
- Phenazone
- Theophylline
- Naltrexone
- Alcohol

Taking Nabilone with food, drinks and alcohol

Nabilone should not be taken in combination with alcohol.

Pregnancy, breast-feeding and fertility

Tell your doctor before you start treatment:

- if you are pregnant, if you think that you are pregnant, or if you intend to become pregnant
- if you are breast-feeding or planning to breast-feed.

There are insufficient data available to assess the safety of using Nabilone during pregnancy. It is not known whether Nabilone is excreted in breast milk.

The use of Nabilone during pregnancy is not recommended and should only be used on the advice of a physician. If treatment is necessary during breastfeeding, breastfeeding must be discontinued during treatment and for 7 days afterward.

There are no data on the effect of Nabilone, the active ingredient in Nabilone, on fertility in humans. Animal studies have shown an effect on fertility for similar active ingredients.

Driving and using machines

Nabilone may cause side effects such as sleepiness, confusion, hallucinations, a feeling of dizziness or spinning, poor muscle co-ordination, problems with your sight and problems with concentration. These side effects may occur up to 3 days after taking Nabilone. This may impair mental and physical abilities required for activities requiring increased attention (e.g., driving a motor vehicle or operate machinery. Do not operate machinery if you experience any of these side effects.

The effect of Nabilone after oral administration can vary and last for an unpredictable length of time.

The medicine can affect your ability to drive as it may make you sleepy or dizzy. Do not drive while taking this medicine until you know how it affects you. It is an offence to drive if this medicine affects your ability to drive.

However, you would not be committing an offence if the medicine has been prescribed to treat a medical or dental problem and if:

- you have taken it according to the instructions given by the prescriber or in the information provided with the medicine and,
- it was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3. How to take Nabilone

Always take Nabilone exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure how to take it. Your doctor will usually start you on the lowest possible dose (1 capsule daily). It is best if you take Nabilone in hospital, especially the first time that you take Nabilone. This is because you may experience side effects.

The hospital doctor or nurse may give you your first dose the evening before you start chemotherapy and the second dose one to three hours before it begins. Swallow the capsules with water.

Dose

- The usual dose is 1mg or 2 mg twice a day.

- You should never take more than 2 mg three times a day. You can take Nabilone while you are having chemotherapy treatment and for up to 2 days after your last dose of chemotherapy.

The dosing recommendations for elderly patients are the same as for other adults.

Elderly patients

There are insufficient data from clinical trials on the use of Nabilone in patients aged 65 years and older; the dose for elderly patients should be selected with caution.

Children and adolescents

There are no data on the safety and efficacy of Nabilone in children and adolescents under 18 years of age.

Patients with liver impairment

No data are available. Use should be undertaken with caution. Use is not recommended in patients with severe liver impairment.

Patients with renal impairment

No data are available. Use should be undertaken with caution.

If you take more Nabilone than you should

If you ever take too many capsules, tell your doctor or get someone to take you to the nearest hospital casualty department immediately together with your medicine to show to the doctor. In case of a severe overdose, symptoms such as psychotic reactions, respiratory depression, and coma may occur. Your doctor will treat the symptoms.

If you forget to take Nabilone

If you miss a dose, wait until it is time for the next dose, and then continue as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Nabilone

Do not stop taking Nabilone without consulting your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Nabilone can cause side effects, although not everybody gets them. To minimize side effects, it is recommended to start treatment with a low dose (1 capsule) and increase it if necessary.

Common (may affect up to 1 in 10 people):

Sleepiness

Disturbance of movement sequences

Headaches

Increased happiness

Sleep disturbance

Irritable mood

Visual impairment
Dizziness
Low blood pressure
Dry mouth
Nausea

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

Impaired coordination
Tremors
Confusion
Disorientation
Hallucinations
Mental disorders
Depression
Anxiety
Feeling Strange
Decreased appetite
Increased heart rate
Abdominal pain

Nabilone is potentially addictive. Therefore, its use must be limited to the necessary duration (a few days) during chemotherapy.

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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Nabilone

- Keep this medicine out of the sight and reach of children.
- Do not use Nabilone after the expiry date which is stated on the bottle or blister and carton after “EXP”. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- If your doctor tells you to stop taking the capsules, please take them back to the pharmacist.
- 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 Nabilone contains

- The active substance is nabilone.
Each 0.25mg capsule contains 0.25mg of nabilone.
Each 1 mg capsule contains 1 mg of nabilone.

- The other ingredients are:
povidone, pregelatinised-starch, isopropyl alcohol, gelatin, water, indigo carmine (E132), quinoline yellow (E104), titanium dioxide (E171), shellac, propylene glycol, black iron oxide (E172), potassium hydroxide. The 0.25mg capsules also contain quinoline yellow (E104) and the 1 mg capsules also contain iron oxide red (E172).

What Nabilone looks like and contents of the pack

Nabilone 0.25 mg capsules: Opaque green, size 2 hard gelatin capsule cap imprinted with “NAB 0.25” and opaque white body imprinted with “NAB 0.25”.

Nabilone 1 mg capsules: Opaque blue, size 2 hard gelatin capsule cap imprinted with “NAB 1” and opaque white body imprinted with “NAB 1”.

They are supplied in bottles or blisters of 20 capsules.

Marketing Authorisation Holder and Manufacturer

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