

**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 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).

Tell your doctor before you start treatment if you have any of the following problems or if you develop any of these during treatment:

- any liver problems
- high blood pressure or any other heart problems

- any mental illness, for example depression or schizophrenia.

### **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 with alcohol**

Do not drink alcohol while you are taking Nabilone.

### **Pregnancy and breast-feeding**

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.

Your doctor will decide if you can take this medicine.

### **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 affect your ability to operate machinery. Do not operate machinery if you experience any of these side effects.

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. 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 night 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 2mg twice a day.
- You should never take more than 2mg 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.

## **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.

## **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.

## **4. Possible side effects**

Like all medicines, Nabilone can cause side effects, although not everybody gets them. Side effects that you may experience are:

- feeling sleepy, relaxed, or “high”. A few patients have had hallucinations, felt confused, depressed, anxious or had other changes in their mood or mental state.
- a feeling of dizziness or spinning, especially when you stand up
- poor muscle co-ordination
- dry mouth, problems with your sight or concentration, difficulty sleeping, or headaches
- shaking, a faster heart beat than normal, low blood pressure, losing your appetite and stomach pains.

Any changes in your mood, such as feeling depressed, relaxed or “high”, may last for 2 or 3 days after you stop taking Nabilone. You may find that you get used to these feelings.

## **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). 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.
- 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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