PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Canemes capsules 1 mg

Active ingredient:
Each Canemes capsule contains:
Nabilone 1 mg
For a list of inactive and allergenic ingredients in the preparation – see section 6 "Further Information".
Read the leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of nausea and vomiting caused by the use of chemotherapy in adult cancer patients who do not respond well to other anti-nausea treatments.

Therapeutic group: Nabilone is a synthetic cannabinoid (artificially manufactured from the cannabis plant) with an effect against nausea and vomiting.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:
- you are sensitive (allergic) to the active ingredient nabilone, to natural cannabinoids, or to any of the additional ingredients contained in the medicine (see section 6 of the leaflet).

Special warnings regarding use of the medicine
❗ Before treatment with Canemes, tell the doctor if:
- You suffer from severely reduced liver function. Its use is not recommended (see also section 3 of the leaflet).
- You suffer from reduced kidney function.
- You have a history of abusing drugs, medicines or alcohol, or of alcohol dependence.
- You are elderly or suffer from hypertension or heart disease, since the medicine could cause hypotension upon standing up (postural hypotension).
- You suffer from mental illness (including bipolar disorder and depression). Do not use Canemes if you suffer from mental illness.

Patients being treated with this preparation must be closely monitored, and if possible, the treatment should take place during hospitalization, since severe and unexpected side effects could occur, especially on initial administration **and after a change in the dosage regimen**.

❗ Children and adolescents
Canemes is not intended for children and adolescents below the age of 18 years, as no information is available regarding the safety and efficacy of use of this preparation in children and adolescents.

❗ Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially of you are taking:
During concomitant use with cannabinoids, drug interactions with the following substances were observed:
- Certain antidepressants (fluoxetine, amitriptyline, desipramine, and other tricyclic antidepressants)
- Certain sedatives/sleeping pills (barbiturates, diazepam and other benzodiazepines, buspirone)
- Certain stimulants (amphetamines, cocaine, other sympathomimetic substances)
- Medicinal substances called anticholinergics (atropine, scopolamine and others)
- Certain pain killers (such as codeine, and opioid and non-opioid analgesics)
- Certain medicinal substances that cause relaxation of skeletal muscles (muscle relaxants)
- Theophylline (used for the treatment of asthma and other respiratory diseases)
- Naltrexone (used for the treatment of opioid and alcohol dependence)
- Disulfiram (used for the treatment of alcohol dependence)
- Lithium (used for the treatment of depression and bipolar disorder)
- Antihistamines (used for the treatment of allergies as well as in the protective treatment of the stomach)
- Other central nervous system depressants (such as chlorpromazine, which is used, among other things, for the treatment of psychosis)

❗ Use of the medicine and alcohol consumption
Do not take Canemes in combination with alcohol.

❗ Pregnancy, breastfeeding and fertility:
Fertility:
Animal studies have not shown a direct or indirect harmful effect on the reproductive system.
Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult with a doctor or pharmacist before using this medicine.
There is insufficient information regarding the use of Canemes during pregnancy. This preparation may be used in case of clinical need during pregnancy, but only after consultation with the doctor.
It is not known whether Canemes passes into breast milk. If treatment is necessary while breastfeeding, breastfeeding should be discontinued beforehand.

❗ Driving and operating machinery:
Do not drive or operate dangerous machines while using the medicine as it may impair the physical and mental capabilities required to perform actions that require increased concentration (e.g. driving or operating machines).
After it is taken, Canemes could have an effect for a variable and unpredictable amount of time.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only. The usual dose is generally:
1-2 capsules twice per day.
Take a low dose (one capsule per day) at the beginning of treatment, and then increase the dose as needed.
Take the first dose the evening before beginning chemotherapy, and the second dose one to three hours before beginning chemotherapy.
Do not consume more than a maximal dose of 3 capsules twice per day (6 capsules per day).

Do not exceed the recommended dosage.

Elderly patients
The dose does not need to be adjusted.

Children and adolescents
Canemes is not intended for use in children and adolescents below the age of 18 as there is no information available regarding the safety and efficacy of Canemes in children and adolescents aged less than 18 years.

Patients with reduced liver function
Use is not recommended in patients with severely reduced liver function.

Patients with reduced kidney function
Use the medicine with caution.

Crushing/halving/chewing:
There is no information about opening and dispersing the contents of the capsule.

If you accidentally take too high a dose, refer immediately to the doctor. In an extreme overdose, symptoms such as psychotic reactions, respiratory depression and coma could occur. The doctor will treat these symptoms.
If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take the medicine, do not take a double dose. Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine
Nabilone has the potential for addiction. Its use should therefore be limited to the required period (a few days) during chemotherapy.
Do not stop taking the medicine without consulting the doctor who is treating you.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Canemes may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
In order to reduce side effects, it is recommended to use a low dose (one capsule) at the beginning of treatment, and then increase the dose as needed.

Common side effects – effects that occur in more than one user in ten:
Somnolence
Lack of coordination of movement
Concentration difficulties
Headache
Euphoria
Sleep disturbances
Despondency and distress
Visual disturbances
Vertigo
Low blood pressure
Dry mouth
Nausea

Rare side effects – effects that occur in 1-10 in 10,000 users:
Coordination problems
Tremor
Confusion
Disorientation
Hallucinations
Psychosis
Depression
Anxiety
Depersonalization disorder
Loss of appetite
Increased heart rate
Abdominal pain

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:
- Do not store at a temperature above 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains–
Contents of the capsule:
Corn starch, pre-gelatinised, Povidone.
Capsule shell:
Gelatine, Titanium dioxide (E 171), Yellow iron oxide (E 172).

What the medicine looks like and contents of the package –
Opaque capsules, colored white (capsule body) and yellow (capsule cap), containing white powder.
Package: 28 capsules packed in polyethylene (HDPE) bottles.

Registration holder and its address:
Truemed Ltd.
10 Benny Gaon St., Poleg Industrial Park
P.O. Box 8105, South Netanya 4250499 Israel.

Name of Manufacturer and its address:
AOP Orphan Pharmaceuticals AG, Wilhelminenstraße, Vienna, Austria.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 164-24-35309

This leaflet was checked and approved by the Ministry of Health in 04.20