

Package leaflet: Information for the user

Vellofent 67 micrograms, sublingual tablets
Vellofent 133 micrograms, sublingual tablets
Vellofent 267 micrograms, sublingual tablets
Vellofent 400 micrograms, sublingual tablets
Vellofent 533 micrograms, sublingual tablets
Vellofent 800 micrograms, sublingual tablets
fentanyl

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Vellofent is and what it is used for

Vellofent contains the active ingredient fentanyl, which belongs to a group of strong pain-relieving medicines called opioids.

Vellofent is used to treat breakthrough pain in adult patients with cancer who are already taking other opioid pain medicines for their persistent (around-the-clock) cancer pain.

Breakthrough pain is additional, sudden pain that occurs even though you have taken your usual opioid pain-relieving medicines.

2. What you need to know before you take Vellofent

Do not take Vellofent:

- if you are allergic to fentanyl or any of the other ingredients of this medicine (listed in section 6);
- if you have severe breathing problems or severe lung disorder;
- if you are currently taking monoamine-oxidase (MAO) inhibitor medicines for severe depression (or have taken them in the past 2 weeks),
- If you are not regularly using a prescribed opioid medicine (e.g codeine, fentanyl, hydromorphone, morphine, oxycodone, pethidine), every day on a regular schedule, for at least a week, to control your persistent pain. If you have not been using these medicines you **must not** use Vellofent, because it may increase the risk that breathing could become dangerously slow and/or shallow, or even stop.
- If you suffer from short-term pain other than breakthrough pain,
- If you are treated with medicinal products containing sodium oxybate.

Warnings and precautions

Vellofent contains an active ingredient in an amount that can be fatal to a child, and therefore keep all tablets out of the sight and reach of children and non-patients at all times.

Keep the tablets in a locked storage space and do not store the tablets once removed from the blister package. Talk to your doctor or pharmacist before taking Vellofent.

Store this medicine in a safe and secure place, where other people cannot access it (see section 5. How to store Vellofent for more information).

Tell your doctor before treatment if you have or have recently had any of the following, as your doctor will need to take account of these when prescribing your dose:

- your other opioid pain medicine taken for your persistent (around-the-clock) cancer pain is not stabilized yet;
- you are suffering from any condition that has an effect on your breathing (such as asthma, wheezing, or shortness of breath);
- you have a head injury;
- you have problems with your heart, especially slow heart rate, irregular heartbeat, low blood volume or low blood pressure;
- you have liver or kidney problems, as these organs have an effect on the way in which your system breaks down the medicine;
- if you take antidepressants or antipsychotics, please refer to the section “Other medicines and Vellofent”.

Consult your doctor while using Vellofent if:

- you experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine as prescribed by your doctor.
- you experience a combination of the following symptoms: nausea, vomiting, anorexia, fatigue, weakness, dizziness and low blood pressure. Together these symptoms may be a sign of a potentially life-threatening condition called adrenal insufficiency, a condition in which the adrenal glands do not produce enough hormones.
- you have ever developed adrenal insufficiency or lack of sex hormones (androgen deficiency) with opioid use.

Long-term use and tolerance

This medicine contains fentanyl which is an opioid medicine. Repeated use of opioid painkillers can result in the drug being less effective (you become accustomed to it, known as drug tolerance). You may also become more sensitive to pain while using Vellofent. This is known as hyperalgesia. Increasing the dose of Vellofent may help to further reduce your pain for a while, but it may also be harmful. If you notice that your medicine becomes less effective, talk to your doctor. Your doctor will decide whether it is better for you to increase the dose or to gradually decrease your use of Vellofent.

Dependence and addiction

This medicine contains fentanyl, which is an opioid. It can cause dependence and/or addiction.

Repeated use of Vellofent can also lead to dependence, abuse and addiction which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use. Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to use or how often you need to use it. You might feel that you need to carry on using your medicine, even when it doesn't help to relieve your pain.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Vellofent if:

You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").

You are a smoker.

You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illness.

If you notice any of the following signs whilst using Vellofent, it could be a sign that you have become dependent or addicted.

You need to use the medicine for longer than advised by your doctor

You need to use more than the recommended dose

You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'

You have made repeated, unsuccessful attempts to quit or control the use of the medicine

When you stop taking the medicine you feel unwell (e.g. nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating), and you feel better once using the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely.

Sleep-related breathing disorders

Vellofent can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Children and adolescents

Vellofent shall not be used by children and adolescents below 18 years.

Other medicines and Vellofent

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

- Monoamine-oxidase (MAO) inhibitors (used for severe depression), see "Do not take Vellofent" above. Tell your doctor if you have taken this type of medicine within the last two weeks,
- Sleeping pills, medicines to treat anxiety, antihistamines, tranquillisers, some muscle relaxants or any medicines which might normally make you sleepy (have a sedative effect), and some painkillers for nerve pain (gabapentin and pregabalin),
- Any medicines that might influence the effect of Vellofent (by effecting the way in which your body breaks down Vellofent), such as:
 - medicines that help control HIV infection (such as ritonavir, indinavir, nelfinavir, saquinavir),
 - medicines used for treatment of fungal infections (such as ketoconazole, itraconazole, or fluconazole),
 - medicines for treatment of bacterial infections (such as clarithromycin, erythromycin, telithromycin) including tuberculosis (such as rifabutin, rifampin),
 - medicines used against severe nausea (such as aprepitant, dronabinol),
 - medicines for treatment of high blood pressure or heart diseases (such as diltiazem and verapamil),
 - medicines used for depression (such as fluoxetine or St. John's wort),
 - medicines used for heartburn and indigestion (such as cimetidin),

- sleeping pills or sedatives (such as phenobarbital),
 - medicines to control epileptic convulsions/seizures (such as carbamazepine, phenytoin, oxcarbazepine),
 - anti-viral medicines (such as efavirenz, nevirapine),
 - anti-inflammatory or immunosuppressive medicines (such as glucocorticoids),
 - medicines for the treatment of diabetes (such as pioglitazone),
 - psycho-stimulating medicines (such as modafinil).
- Certain types of strong pain killers, called partial agonist/antagonists e.g. buprenorphine, nalbuphine, pentazocine (medicines for treatment of pain). You could experience symptoms of withdrawal syndrome (nausea, vomiting, diarrhea, anxiety, chills, tremor, and sweating) while using these medicines. These medicines may reduce or reverse the effect of Vellofent.
- The risk of side effects increases if you are taking medicines such as certain antidepressants or antipsychotics. Vellofent may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea). Your doctor will tell you whether Vellofent is suitable for you.
- Concomitant use of Vellofent and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Vellofent together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.
- Concomitant use of medicinal products containing sodium oxybate and fentanyl is contraindicated (see the section "Do not take Vellofent"). The treatment of sodium oxybate should be discontinued before start of treatment with Vellofent.

Vellofent with food, drink and alcohol

- Vellofent may be used before or after, but not during, meals. You may drink some water before using Vellofent to help moisten your mouth, but you should not drink or eat anything while taking the medicine.
- You should not drink grapefruit juice while using Vellofent because it may affect the way your body breaks down Vellofent.
- Do not drink alcohol while using Vellofent. It can increase the risk of experiencing dangerous side effects.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Vellofent should not be used during pregnancy unless you have discussed this with your doctor. You should not use Vellofent during childbirth because fentanyl may cause respiratory depression and withdrawal symptoms in the fetus or in the new-born child.

Fentanyl can get into breast milk and may cause side effects in the breast-fed infant. Do not use Vellofent if you are breast-feeding. You should not start breast-feeding until at least 5 days after the last dose of Vellofent.

Driving and using machines

You should discuss with your doctor whether it is safe for you to drive, or operate machinery after taking Vellofent. Do not drive or operate machinery if you: are feeling sleepy or dizzy; have blurred or double vision; or have difficulty in concentrating. It is important you know how you react to Vellofent before driving or operating machinery.

Vellofent contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium free’.

3. How to take Vellofent

Before starting treatment and regularly during treatment, your doctor will also discuss with you what you may expect from using Vellofent, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also section 2).

This medicine should be taken by placing the tablet under your tongue (sublingual use).

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If your doctor switched you to Vellofent, you must not use the previous medicine containing fentanyl concurrently for the treatment of your breakthrough pain. Dispose of the previous medicine. However, keep using the opioid pain medicine you take for your persistent (around-the-clock) cancer pain during your Vellofent treatment.

Initial Phase – Finding the most appropriate dose

For Vellofent to work successfully, your doctor will need to identify the most appropriate dose for treating a single episode of breakthrough pain. Vellofent sublingual tablets are available in a range of strengths. You may need to try different strengths of Vellofent sublingual tablets over a number of episodes of breakthrough pain to find the most appropriate dose. Your doctor will help you do this and will work with you to find the best strength of tablet to use.

If you do not get adequate pain relief from one tablet your doctor may ask you to take two tablets to treat an episode of breakthrough pain. Do not take a second tablet unless your doctor tells you to as this may result in overdose. Your doctor will advise you which strength of tablet to use.

You must always use the dose of Vellofent as prescribed by your doctor – this may be a different dose from that which you have used with other medicines for breakthrough pain.

Maintenance Phase - Once you have found the most appropriate dose

Once you and your doctor have found a dose of Vellofent tablets that controls your breakthrough pain you should not take this dose more than four times a day. **A dose of Vellofent may consist of more than one tablet.**

If you think that the dose of Vellofent that you are using is not controlling your breakthrough pain satisfactorily tell your doctor, as he may need to adjust your dose.

You must not change your dose of Vellofent unless directed by your doctor.

Taking the medicine

Vellofent should be used sublingually. This means that the tablet should be placed under the tongue where it dissolves rapidly in order to allow fentanyl to be absorbed across the lining of the mouth.

When you get an episode of breakthrough pain, take the dose advised by your doctor as follows:

- If your mouth is dry, take a sip of water to moisten it. Spit out or swallow the water.
- Remove the tablet(s) from the blister pack immediately before use.
- Peel back the tab of the foil top of one blister as shown on the blister foil and gently remove the tablet. Do not try to push Vellofent sublingual tablets through the foil top.
- Place the tablet under your tongue as far back as you can and let it dissolve completely.

- Vellofent will dissolve rapidly under the tongue and be absorbed in order to provide pain relief. It is therefore important that you do not suck, chew or swallow the tablet.
- After 30 minutes, if pieces of the tablet remain, they may be swallowed.
- You should not drink or eat anything until the tablet has completely dissolved under your tongue.

If you take more Vellofent than you should

- remove any remaining tablets from your mouth,
- tell your caregiver or another person what has happened,
- you or your caregiver should immediately contact your doctor, pharmacist or local hospital and discuss what action to take

Symptoms of overdose include altered mental status, loss of consciousness, extreme drowsiness, slow and shallow breathing. If these occur, seek emergency medical help immediately.

An overdose may also result in a brain disorder known as toxic leukoencephalopathy.

Note to caregivers

While waiting for the doctor:

- keep the person awake by talking to or shaking her/him now and then,
- make sure the person has free airways and is breathing.

If you think someone has taken Vellofent by accident, seek emergency medical help immediately.

If you forget to take Vellofent

Do not take a double dose to make up for a forgotten tablet.

If you stop using Vellofent

You should discontinue Vellofent when you no longer have any breakthrough pain. You must however continue to take your usual opioid pain relieving medicine to treat your persistent cancer pain as advised by your doctor. You may experience withdrawal symptoms similar to the possible side effects of Vellofent when discontinuing Vellofent. If you experience withdrawal symptoms or if you are concerned about your pain relief you should contact your doctor. Your doctor will evaluate if you need medicine to reduce or eliminate the withdrawal symptoms.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most serious side effects are

- shallow and slow breathing (uncommon, may affect up to 1 in 100 people),
- low or extremely low blood pressure and shock.

If you become very sleepy and/or experience any of the above mentioned side effects, you should stop taking Vellofent and you or your caregiver should contact your doctor immediately and call for emergency help.

Other side effects that may occur:

Very common (may affect more than 1 in 10 people):

- nausea,
- constipation,
- sleepiness,
- sedation,
- dizziness.

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

- confusion, anxiety, seeing or hearing things that are not really there (hallucinations), abnormal thinking,
- asthenia (weakness),
- headache, muscle jerks, feeling of dizziness or “spinning”, loss of consciousness,
- dry mouth, taste alteration,
- low blood pressure,
- vomiting, abdominal pain, indigestion,
- sweating, itchy skin,
- fall.

Uncommon (may affect up to 1 in 100 people):

- decreased appetite, wind, abdominal bloating, tooth decay, blockage of the gut (ileus),
- malaise,
- tingling or numbness, difficulty coordinating movements, convulsions (fits), coma,
- abnormal dreams, feeling detached, depression, mood swings, excessive feeling of well-being,
- severe breathing problems,
- blurred or double vision,
- skin rash, increased or altered sensitivity to touch,
- difficulty passing urine.

Not known (frequency cannot be estimated from the available data):

- receding gums, tooth loss
- flushing,
- feeling very warm,
- diarrhoea,
- swelling of arms or legs,
- fatigue,
- insomnia,
- pyrexia,
- withdrawal syndrome (may manifest by the occurrence of the following side effects nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating),
- drug dependence (addiction) (see section 2),
- drug abuse (see section 2),
- delirium (symptoms may include a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares)
- drug tolerance (see section 2).

Prolonged treatment with fentanyl during pregnancy may cause withdrawal symptoms in the newborn which can be life-threatening (see section 2).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Vellofent

The pain-relieving medicine in Vellofent is very strong and could be life-threatening if taken accidentally by a child. Keep this medicine out of the sight and reach of children.

Store this medicine in a safe and secure place, where other people cannot access it. It can cause serious harm and be fatal to people who may take this medicine by accident, or intentionally when it has not been prescribed for them.

Keep Vellofent in a locked storage space.

Do not use this medicine after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store in the original blister package, in order to protect from light.

Do not store the tablet once removed from the blister package.

Unused or partially used remaining products must not be disposed of via wastewater or household waste. It should be taken, if possible, to your pharmacist to be disposed of safely. This is a safety precaution and it will also help protect the environment.

6. Contents of the pack and other information

What Vellofent contains

- The active substance is: fentanyl.

Each sublingual tablet contains 67, 133, 267, 400, 533 or 800 micrograms of fentanyl (as citrate).

- The other ingredients (excipients) are: calcium hydrogen phosphate anhydrous, microcrystalline cellulose, disodium phosphate anhydrous, hypromellose, macrogol, magnesium stearate, maltodextrin, titanium dioxide (E171), triacetin, printing ink (shellac, iron oxide black (E172)).

What Vellofent looks like and contents of the pack

Vellofent 67 micrograms is a white, convex, triangular tablet, height of 5.6 mm, printed with ‘0’ in black ink on one face.

Vellofent 133 micrograms is a white, convex, triangular tablet, height of 5.6 mm, printed with ‘1’ in black ink on one face.

Vellofent 267 micrograms is a white, convex, triangular tablet, height of 5.6 mm, printed with ‘2’ in black ink on one face.

Vellofent 400 micrograms is a white, convex, triangular tablet, height of 5.6 mm, printed with ‘4’ in black ink on one face.

Vellofent 533 micrograms is a white, convex, triangular tablet, height of 5.6 mm, printed with ‘5’ in black ink on one face.

Vellofent 800 micrograms is a white, convex, triangular tablet, height of 5.6 mm, printed with ‘8’ in black ink on one face.

The Vellofent sublingual tablets are available in a peelable, child resistant blister, with pack sizes of 3, 4, 15 or 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden: Vellofent

Bulgaria: Vellofent
Czech Republic: Vellofent
Greece: Vellofent
Spain: Avaric
Italy: Vellofent
Poland: Vellofent
Portugal: Vellofent

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Instruction for Use on this product is available by scanning the QR code included in the outer carton with a smartphone/device. The same information is also available on the following URL: [URL to be included]