



DUROGESIC 25 micrograms/hour transdermal patch
DUROGESIC 50 micrograms/hour transdermal patch
DUROGESIC 100 micrograms/hour transdermal patch

Summary

Long-term use and tolerance

This medicine contains fentanyl which is an opioid medicine. Repeated use of opioid pain killers 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 DUROGESIC. This is known as hyperalgesia. Increasing the dose of your patches 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 DUROGESIC.

Dependence and addiction

Repeated use of DUROGESIC 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 DUROGESIC 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 DUROGESIC, 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, 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.

-Before starting treatment and regularly during treatment, your doctor will also discuss with you what you may expect from using DUROGESIC, when and how long you need to take it, when to contact your doctor, and when you need to stop it.

Call for reporting

Jordan Food and Drug Administration (JFDA)

Email: jpc@jfda.jo

Website: <http://www.jfda.jo/>

Electronic reporting form: <https://primaryreporting.who-umc.org/JO>

Tel: +962-6-5632000

QR Code



Company contact points

Janssen scientific office:

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E-mail: JACEG-PV@its.jnj.com **Adverse events related to DUROGESIC should be reported to**

Janssen PV department

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