Footnotes 2, 3, 4

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Summary of Product Characteristics last updated on the eMC: 17/03/2009

SPC Durogesic DTrans 12/25/50/75/100

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Legal Categories
› POM – Prescription Only Medicine

Active Ingredients/Generics
› fentanyl

1. NAME OF THE MEDICINAL PRODUCT

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Durogesic® DTrans® 12/25/50/75/100 mcg/hr Transdermal Patch

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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Each Durogesic DTrans 12/25/50/75/100 patch contains fentanyl 2.1/4.2/8.4/12.6/16.8 mg.

Release rate approximately 12/25/50/75/100 µg/h; active surface area 5.25/10.5/21.0/31.5/42.0 cm^2.

For excipients, see 6.1

3. PHARMACEUTICAL FORM

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Transdermal patch.

4. CLINICAL PARTICULARS

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4.1 Therapeutic indications

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Durogesic DTrans is indicated

- in the management of chronic intractable pain due to cancer

- in the management of chronic intractable pain

4.2 Posology and method of administration

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For transdermal use.

Durogesic DTrans should be applied to non-irritated and non-irradiated skin on a flat surface of the torso or upper arm. In young children, the upper back is the preferred location to apply the patch, to minimise the potential of the child removing the patch. A non-hairy area should be selected. If this is not possible, hair at the application site should be clipped (not shaved) prior to application. If the site of Durogesic DTrans application requires to be cleansed prior to application of the patch, this should be done with water. Soaps, oils, lotions or any other agent that might irritate the skin or alter its characteristics should not be used. The skin should be completely dry before the patch is applied. Patches should be inspected prior to use. Patches that are cut, divided, or damaged in any way should not be used.

The Durogesic DTrans patch should be removed from the protective pouch by first folding the notch (located close to the tip of the arrow on the pouch label) and then carefully tearing the pouch material. If scissors are used to open the pouch, this should be done close to the sealed edge so as not to damage the patch inside.

Durogesic DTrans should be applied immediately after removal from the sealed pouch. Avoid touching the adhesive side of the patch. Following removal of both parts of the protective liner, the transdermal patch should be pressed firmly in place with the palm of the hand for approximately 30 seconds, making sure the contact is complete, especially around the edges. Then wash hands with clean water.

Durogesic DTrans should be worn continuously for 72 hours. A new patch should then be applied to a different skin site after removal of the previous transdermal patch. Several days should elapse before a new patch is applied to the same area of skin.

The need for continued treatment should be assessed at regular intervals.

Adults:

Initial dose selection

It is recommended that Durogesic DTrans be used in patients who have previously tolerated opioids. The initial Durogesic DTrans dose should be based on the patient's opioid history, including the degree of opioid tolerance, if any, as well as on the current general condition and medical status of the patient.

In strong opioid-naive patients, Durogesic DTrans dose 25 µg/h should be used as the initial dose.

Clinical experience with Durogesic DTrans is limited in opioid-naïve patients. If therapy with Durogesic DTrans is considered appropriate in opioid-naïve patients, it is recommended that these patients be titrated with low doses of short-acting opioids initially. Patients can then be converted to Durogesic DTrans 25 mcg/hr. The dose may subsequently be titrated upwards or downwards, if required, in increments of 12 or 25 mcg/hr to achieve the lowest appropriate dose of Durogesic DTrans depending on the response and supplementary analgesic requirements (see also section 4.4).

In opioid-tolerant patients, the initial dose of Durogesic DTrans should be based on the previous 24 hour opioid analgesic requirement. A recommended conversion scheme from oral morphine to Durogesic DTrans is given below in Table 1:

Table 1: Recommended Durogesic DTrans dose based upon daily oral morphine dose

Oral 24-Hour Morphine (mg/day)	**Durogesic DTrans (µg/h)**
<90	25
90 - 134	37
135 - 189	50
190 - 224	62
225 - 314	75
315 - 404	100
405 - 494	125
495 - 584	150
585 - 674	175
675 - 764	200
765 - 854	225
855 - 944	250

945 – 1034	275
1035 - 1124	300

Previous analgesic therapy should be phased out gradually from the time of the first patch application until analgesic efficacy with Durogesic DTrans is attained. For both strong opioid-naïve and opioid tolerant patients, the initial evaluation of the analgesic effect of Durogesic DTrans should not be made until the patch has been worn for 24 hours due to the gradual increase in serum fentanyl concentrations up to this time.

Dose titration and maintenance therapy

The Durogesic DTrans patch should be replaced every 72 hours. The dose should be titrated individually until analgesic efficacy is attained. If analgesia is insufficient at the end of the initial application period, the dose may be increased. Dose adjustment, when necessary, should normally be performed in the following titration steps from 25 µg/h up to 75 µg/h: 25 µg/h, 37 µg/h, 50 µg/h, 62 µg/h and 75 µg/h; thereafter dose adjustments should normally be performed in 25 µg/h increments, although the supplementary analgesic requirements (oral morphine 90 mg/day ≈ Durogesic DTrans 25 µg/h) and pain status of the patient should be taken into account. More than one Durogesic DTrans patch may be used to achieve the desired dose. Patients may require periodic supplemental doses of a short-acting analgesic for 'breakthrough' pain. Additional or alternative methods of analgesia should be considered when the Durogesic DTrans dose exceeds 300 µg/h.

Discontinuation of Durogesic DTrans

If discontinuation of Durogesic DTrans is necessary, any replacement with other opioids should be gradual, starting at a low dose and increasing slowly. This is because fentanyl levels fall gradually after Durogesic DTrans is removed. After system removal, serum fentanyl concentrations decline gradually with mean terminal half-life ranging from 22-25 hours. As a general rule, the discontinuation of opioid analgesia should be gradual, in order to prevent withdrawal symptoms.

Opioid withdrawal symptoms (See section 4.8) are possible in some patients after conversion or dose adjustment.

Use in elderly patients

Data from intravenous studies with fentanyl suggest that elderly patients may have reduced clearance, a prolonged half-life and they may be more sensitive to the drug than younger patients. Studies of Durogesic DTrans in elderly patients demonstrated fentanyl pharmacokinetics which did not differ significantly from young patients although serum concentrations tended to be higher. Elderly, cachectic, or debilitated patients should be observed carefully for signs of fentanyl toxicity and the dose reduced if necessary.

Paediatric Patients:

Durogesic DTrans should be administered only to **opioid-tolerant paediatric patients (ages 2 to 16 years)** who are already receiving at least 30 mg oral morphine equivalents per day. To convert paediatric patients from oral opioids to Durogesic DTrans refer to Table 2, Recommended Durogesic DTrans dose based upon daily oral morphine dose.

Table 2: Recommended Durogesic DTrans dose based upon daily oral morphine dose[1]

Oral 24-Hour Morphine (mg/day)	**Durogesic DTrans (µg/h)**
For paediatric patients[2]	
30 - 44	12
45 - 134	25

[1] In clinical trials these ranges of daily oral morphine doses were used as a basis for conversion to Durogesic DTrans

[2] Conversion to Durogesic DTrans doses greater than 25 µg/h is the same for adult and paediatric patients

For children who receive more than 90 mg oral morphine a day, only limited information is currently available from clinical trials. In the paediatric studies, the required fentanyl transdermal patch dose was calculated conservatively: 30 mg to 44 mg oral morphine per day or its equivalent opioid dose was replaced by one Durogesic DTrans 12 patch. It should be noted that this conversion schedule for children only applies to the switch from oral morphine (or its equivalent) to Durogesic DTrans patches. The conversion schedule should not be used to convert from Durogesic DTrans into other opioids, as overdosing could then occur.

The analgesic effect of the first dose of Durogesic DTrans patches will not be optimal within the first 24 hours. Therefore, during the first 12 hours after switching to Durogesic DTrans, the patient should be given the previous regular dose of analgesics. In the next 12 hours, these analgesics should be provided based on clinical need.

Since peak fentanyl levels occur after 12 to 24 hours of treatment, monitoring of the patient for adverse events, which may include hypoventilation, is recommended for at least 48 hours after initiation of Durogesic DTrans therapy or up-titration of the dose (see also section 4.4).

Dose titration and maintenance

If the analgesic effect of Durogesic DTrans is insufficient, supplementary morphine or another short-duration opioid should be administered. Depending on the additional analgesic needs and the pain status of the child, it may be decided to increase the dose. Dose adjustments should be done in 12 µg/hour steps.

4.3 Contraindications | Go to top of the page

Durogesic DTrans is contraindicated in patients with known hypersensitivity to fentanyl or to the adhesive in the patch.

Durogesic DTrans is a sustained-release preparation indicated for the treatment of chronic intractable pain and is contraindicated in acute pain because of the lack of opportunity for dosage titration during short term use and the possibility of significant or life-threatening respiratory depression.

4.4 Special warnings and precautions for use

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It is not possible to ensure the interchangeability of different makes of fentanyl transdermal patches in individual patients. Therefore, it should be emphasised that patients should not be changed from one make of fentanyl transdermal patches to another without specific counselling on the change from their healthcare professionals.

Patients who have experienced serious adverse events should be monitored for up to 24 hours after Durogesic DTrans removal since serum fentanyl concentrations decline gradually with mean terminal half-life ranging from 22-25 hours.

Durogesic DTrans should be kept out of reach and sight of children at all times before and after use.

Durogesic DTrans patches should not be cut. No data are available on cut or divided patches.

Use of Durogesic DTrans in opioid-naïve patients has been associated with very rare cases of significant respiratory depression and/or fatality when used as initial opioid therapy. The potential for serious or life-threatening hypoventilation exists even if the lowest dose of Durogesic DTrans is used in initiating therapy in opioid-naïve patients. It is recommended that Durogesic DTrans be used in patients who have demonstrated opioid tolerance (See Section 4.2).

When Durogesic DTrans is administered for chronic intractable pain that will require prolonged treatment, it is strongly recommended that the physician defines treatment outcomes with regards to pain relief and functional improvement in accordance with locally defined pain management guidelines. Physician and patient should agree to discontinue treatment if these objectives are not met.

Respiratory depression

As with all potent opioids, some patients may experience significant respiratory depression with Durogesic DTrans; patients must be observed for these effects. Respiratory depression may persist beyond the removal of the Durogesic DTrans patch. The incidence of respiratory depression increases as the Durogesic DTrans dose is increased (see Section 4.9). CNS active drugs may increase the respiratory depression (see section 4.5).

Interactions with CYP3A4 Inhibitors

The concomitant use of Durogesic DTrans with cytochrome P450 3A4 inhibitors (e.g. ritonavir, ketoconazole, itraconazole, clarithromycin, erythromycin, nelfinavir, verapamil, diltiazem and amiodarone) may result in an increase in fentanyl plasma concentrations, which could increase or prolong both the therapeutic and adverse effects, and may cause serious respiratory depression. In this situation special patient care and observation are appropriate. Therefore the concomitant use of transdermal fentanyl and cytochrome P450 3A4 inhibitors is not recommended unless the patient is closely monitored. Patients, especially those who are receiving Durogesic DTrans and CYP3A4 inhibitors, should be monitored for signs of respiratory depression and dosage adjustments should be made if warranted.

Chronic pulmonary disease

Fentanyl, like other opioids, may have more severe adverse effects in patients with chronic obstructive or other pulmonary disease. In such patients, they may decrease respiratory drive and increase airway resistance.

Drug dependence

Tolerance, physical dependence and psychological dependence may develop upon repeated administration of opioids such as fentanyl. Iatrogenic addiction following opioid administration is rare.

Increased intracranial pressure

Durogesic DTrans should be used with caution in patients who may be particularly susceptible to the intracranial effects of CO_2 retention such as those with evidence of increased intracranial pressure, impaired consciousness or coma. Durogesic DTrans should be used with caution in patients with brain tumours.

Cardiac disease

Fentanyl may produce bradycardia and Durogesic DTrans should therefore be administered with caution to patients with bradyarrhythmias.

Hepatic disease

Because fentanyl is metabolised to inactive metabolites in the liver, hepatic disease might delay its elimination. In patients with hepatic cirrhosis, the pharmacokinetics of a single application of Durogesic DTrans were not altered although serum concentrations tended to be higher in these patients. Patients with hepatic impairment should be observed carefully for signs of fentanyl toxicity and the dose of Durogesic DTrans reduced if necessary.

Renal disease

Less than 10% of fentanyl is excreted unchanged by the kidney and, unlike morphine, there are no known active metabolites eliminated by the kidney. Data obtained with intravenous fentanyl in patients with renal failure suggest that the volume of distribution of fentanyl may be changed by dialysis. This may affect serum concentrations. If patients with renal impairment receive Durogesic DTrans, they should be observed carefully for signs of fentanyl toxicity and the dose reduced if necessary.

Patients with fever/external heat

Patients who develop fever should be monitored for opioid side effects since significant increases in body temperature can potentially increase fentanyl delivery rate.

Patients should also be advised to avoid exposing the Durogesic DTrans application site to direct external heat sources such as heating pads, hot water bottles, electric blankets, heat lamps, saunas or hot whirlpool spa baths while wearing the patch, since there is potential for temperature dependent increases in release of fentanyl from the patch.

Use in Paediatric Patients

Durogesic DTrans should not be administered to opioid-naïve paediatric patients (see section 4.2). The potential for serious or life-threatening hypoventilation exists regardless of the dose of Durogesic DTrans administered (see Table 2 in section 4.2).

Durogesic DTrans has not been studied in children under 2 years of age and so should not be used in these children. Durogesic DTrans should be administered only to opioid-tolerant children age 2 years or older (see section 4.2).

To guard against accidental ingestion by children, use caution when choosing the application site for Durogesic DTrans (see section 4.2) and monitor adhesion of the patch closely.

Patch disposal

Used patches may contain significant residues of active substance. After removal, therefore, used patches should be folded firmly in half, adhesive side inwards, so that the adhesive is not exposed, and then discarded safely and out of the reach of children according to the instructions in the pack.

4.5 Interaction with other medicinal products and other forms of interaction

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The concomitant use of other CNS depressants, including opioids, anxiolytics, hypnotics, general anaesthetics, antipsychotics, skeletal muscle relaxants, sedating antihistamines and alcoholic beverages may produce additive depressant effects; hypoventilation, hypotension and profound sedation, coma or death may occur. Therefore, the use of any of the above mentioned concomitant drugs requires special care and observation.

Fentanyl, a high clearance drug, is rapidly and extensively metabolised mainly by CYP3A4.

The concomitant use of CYP3A4 inhibitors with transdermal fentanyl may result in an increase in fentanyl plasma concentrations, which could increase or prolong both the therapeutic and adverse effects, and may cause serious respiratory depression. In this situation, special patient care and observation are appropriate. The concomitant use of CYP3A4 inhibitors and transdermal fentanyl is not recommended, unless the patient is closely monitored (see Section 4.4).

Monoamine Oxidase Inhibitors (MAOI)

Durogesic DTrans is not recommended for use in patients who require the concomitant administration of an MAOI. Severe and unpredictable interactions with MAOIs, involving the potentiation of opiate effects or the potentiation of serotoninergic effects, have been reported.

4.6 Pregnancy and lactation

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The safety of fentanyl in pregnancy has not been established. Studies in animals have shown some reproductive toxicity. The potential risk for humans is unknown. Durogesic DTrans should not be used during pregnancy unless clearly necessary.

Use of Durogesic DTrans during childbirth is not recommended because fentanyl passes through the placenta and may cause respiratory depression in the newborn child.

Fentanyl is excreted into breast milk and may cause sedation/respiratory depression in the newborn/infant, hence Durogesic DTrans should not be used by women who are breast feeding.

4.7 Effects on ability to drive and use machines

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Durogesic DTrans may impair the mental or physical ability required to perform potentially hazardous tasks such as driving or operating machinery.

4.8 Undesirable effects

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Undesirable effects listed below in Table 3 have been reported in a clinical trial and/or from spontaneous reports from post-marketing experience.

A multicentre, double-blind, randomised, placebo-controlled clinical study (FEN-EMA-1) of Durogesic DTrans examined patients (> 40 years of age) with severe pain induced by osteoarthritis of the hip or knee and who were in need of and waiting for joint replacement. Patients were treated for 6 weeks with Durogesic DTrans by titrating to adequate pain control starting from 25 µg/hr to a maximum dose of 100 µg/hr in 25 µg/hr increments. This treatment was preceded by a 1-week washout period and followed by a tapering-off period of no more than 12 days. The adverse events, regardless of causality, reported by 1% or more of the patients treated with Durogesic DTrans during the trial and reported at a frequency greater than with placebo are presented in Table 3.

The adverse events are ranked by frequency, using the following convention:

Very common ≥ 1/10

Common ≥ 1/100 and <1/10

Uncommon ≥ 1/1,000 and <1/100

Rare ≥ 1/10,000 and <1/1,000

Very Rare <1/10,000

Unknown

Adverse drug reactions from spontaneous reports during worldwide postmarketing experience involving all indications with Durogesic DTrans that met threshold criteria are also included in Table 3. Unlike for clinical trials, precise frequencies cannot be provided for spontaneous reports. The frequency for these reports is therefore classified as 'not known'.

Table 3 Adverse Events, Regardless of Causality, Reported by ≥ 1% of Patients and Reported More Frequently with Durogesic DTrans than with Placebo during Double-Blind Treatment and Adverse Drug Reactions from Postmarketing Spontaneous Reports

Body System/Organ Class *Frequency Category*	Clinical trials	Spontaneous Reports[a]
Immune system disorders		
Not known		Anaphylactic shock, anaphylactic reaction, anaphylactoid reaction
Metabolism and nutrition disorders		
Common	Anorexia	
Psychiatric Disorders		
Very common	Somnolence, insomnia	
Common	Anxiety, depression	
Not known		Confusional state, hallucination, euphoric mood, agitation
Nervous system disorders		
Very common	Dizziness	
Common	Muscle contractions involuntary, hypoaesthesia	
Not known		Convulsions (including clonic convulsions and grand mal convulsion), amnesia, headache, tremor, paraesthesia
Eye disorders		
Common	Conjunctivitis	
Cardiac disorders		
Common	Palpitations	
Not known		Tachycardia, bradycardia
Vascular Disorders		

Not known		Hypotension, hypertension
Respiratory, thoracic, and mediastinal disorders		
Common	Yawning, rhinitis	
Not known		Respiratory depression (including respiratory distress, apnoea, and bradypnoea; (see Section 4.9), hypoventilation, dyspnoea
Gastrointestinal disorders		
Very common	Nausea, vomiting, constipation	
Common	Abdominal pain, dyspepsia, dry mouth	
Not known		Diarrhoea
Skin and subcutaneous tissue disorders		
Common	Pruritis, skin disorder, hyperhidrosis	
Not known		Rash, erythema
Renal and urinary disorders		
Common	Urinary tract infection	
Not known		Urinary retention
Reproductive system and breast disorders		
Not known		Sexual dysfunction
General disorders and administration site conditions		
Common	Feeling of body temperature change, fatigue, malaise, influenza like illness, oedema peripheral, asthenia, drug withdrawal syndrome	Application site reaction
a: Listed are only those adverse drug reactions that were not identified during FEN-EMA-1.		

As with other opioid analgesics, tolerance, physical dependence, and psychological dependence can develop on repeated use of Durogesic DTrans (see Section 4.4).

Opioid withdrawal symptoms (such as nausea, vomiting, diarrhoea, anxiety, and shivering) are possible in some patients after conversion from their previous opioid analgesic to Durogesic DTrans or if therapy is stopped suddenly (see Section 4.2).

The adverse event profile in children and adolescents treated with Durogesic DTrans was similar to that observed in adults. No risk was identified in the paediatric population beyond that expected with the use of opioids for the relief of pain associated with serious illness. There does not appear to be any paediatric-specific risk associated with Durogesic DTrans use in children as young as 2 years old when used as directed. Very common adverse events reported in paediatric clinical trials were fever, vomiting, and nausea.

4.9 Overdose

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Symptoms

The symptoms of fentanyl overdosage are an extension of its pharmacological actions, the most serious effect being respiratory depression.

Treatment

For management of respiratory depression, immediate countermeasures include removing Durogesic DTrans and physically or verbally stimulating the patient. These actions can be followed by administration of a specific opioid antagonist such as naloxone. The interval between IV antagonist doses should be carefully chosen and repeated administration or a continuous infusion of naloxone may be necessary because of continued absorption of fentanyl from the skin after patch removal, which may result in prolonged respiratory depression. Reversal of the narcotic effect may result in acute onset of pain and release of catecholamines.

A patent airway should be established and maintained. An oropharyngeal airway or endotracheal tube and oxygen should be administered and respiration assisted or controlled, as appropriate. Adequate body temperature and fluid intake should be maintained.

If severe or persistent hypotension occurs, hypovolaemia should be considered, and the condition should be managed with appropriate parenteral fluid therapy.

5. PHARMACOLOGICAL PROPERTIES

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5.1 Pharmacodynamic properties

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Pharmacotherapeutic group: opioid analgesic

ATC code: N02A B03

Fentanyl is an opioid analgesic with a high affinity for the μ-opioid receptor.

Paediatric Patients

The safety of Durogesic DTrans was evaluated in three open-label trials in 293 paediatric patients with chronic pain, 2 years of age through to 18 years of age, of which 66 children were aged to 2 to 6 years. In these studies, 30 mg to 44 mg oral morphine per day was replaced by one Durogesic 12 μg/h patch. Starting doses of 25 μg/h and higher were used by 181 patients who had been on prior daily opioid doses of at least 45 mg per dose of oral morphine.

5.2 Pharmacokinetic properties

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Adults

Durogesic DTrans provides continuous systemic delivery of fentanyl over the 72 hour administration period. After the first Durogesic DTrans application, serum fentanyl concentrations increase gradually, generally levelling off between 12 and 24 hours, and remaining relatively constant for the remainder of the 72-hour application period. The serum fentanyl concentrations attained are proportional to the Durogesic DTrans patch size. For all practical purposes, by the second 72-hour application, a steady state serum concentration is reached and is maintained during subsequent applications of a patch of the same size.

After Durogesic DTrans is removed, serum fentanyl concentrations decline gradually, with mean terminal half-life ranging from 22-25 hours. Continued absorption of fentanyl from the skin accounts for a slower disappearance of the drug from the serum than is seen after an IV infusion. Fentanyl is metabolised primarily in the liver. Around 75% of fentanyl is excreted into the urine, mostly as metabolites, with less than 10% as unchanged drug. About 9% of the dose is recovered in the faeces, primarily as metabolites. The major metabolite, norfentanyl, is inactive. Mean values for unbound fractions of fentanyl in plasma are estimated to be between 13 and 21%.

Paediatric Patients

Adjusting for body weight, clearance (L/hr/Kg) in paediatric patients appears to be 82% higher in children 2 to 5 years old and 25% higher in children 6 to 10 years old when compared to children 11 to 16 years old, who are likely to have the same clearance as adults. These findings have been taken into consideration in determining the dosing recommendations for paediatric patients.

5.3 Preclinical safety data

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No relevant information other than that contained elsewhere in the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

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6.1 List of excipients

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Polyacrylate adhesive

Polyethylene terephthalate/ethyl vinyl acetate film

Orange/Red/Green/Blue/Grey printing ink

Siliconised polyester film

6.2 Incompatibilities

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To prevent interference with the adhesive properties of Durogesic DTrans, no creams, oils, lotions or powder should be applied to the skin area when the Durogesic DTrans transdermal patch is applied.

6.3 Shelf life

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2 years.

6.4 Special precautions for storage

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This medicinal product does not require any special storage precautions.

6.5 Nature and contents of container

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Each patch is packed in a heat-sealed pouch made acrylonitrate film, polyethylene terephthalate (PET), low density polyethylene/aluminium foil and adhesive (Adcote 548). Five pouches are assembled in cardboard cartons.

6.6 Special precautions for disposal and other handling

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Please refer to section 4.2 for instructions on how to apply the patch. There are no safety and pharmacokinetic data available for other application sites.

After removal, the used patch should be folded in half, adhesive side inwards so that the adhesive is not exposed, placed in the original sachet and then discarded safely out of reach of children.

Wash hands after applying or removing the patch.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

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PL 00242/0409; PL 00242/0192-5

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Durogesic DTrans 12: 28 October 2005

Durogesic DTrans 25, 50, 75, 100: 4 March 1994/3 March 2009

10. DATE OF REVISION OF THE TEXT

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Durogesic DTrans 12: 13 October 2008

Durogesic DTrans 25, 50, 75, 100: 3 March 2009

Legal category POM/CD2

More information about this product

- Patient Information Leaflets (PILs):

Durogesic DTrans 12/25/50/75/100 Transdermal Patch

- Medicine Guides:
  Durogesic

Link to this document from your website: http://emc.medicines.org.uk/medicine/17086/SPC/Durogesic DTrans 12/25/50/75/100/