Name of the sponsor Laboratoires JANSSEN-CILAG
Trade name of the drug DUROGESIC ®
INN Transdermal fentanyl

Study title	Assessment of the efficacy and tolerance of transdermal Fentanyl in patients with chronic cancer pain in outpatient medicine	
Investigators	General practitioners throughout France.	
Centres	Centres recruited 45 Active centres 21	
Publication		
Schedule	First patient included: 19/09/03 Last patient completed: 29/05/04	
Objective	To assess the efficacy and tolerance of the fentanyl transdermal system and the quality of life of treated patients in strong opioid-naïve cancer patients presenting painful symptoms, resistant to level-2 analgesics.	
Study design	Multicentre open non-comparative study Evaluation of the efficacy of study treatments by self-assessment on a 100-mm VAS scale	
Number of patients	Scheduled: 80 inclusions Intent-to-treat analysis population: 34 Per protocol analysis population: N.A.	

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Inclusion criteria	▪ Male or female patients, ▪ Patients aged 18 years or over, ▪ Patients with demonstrated and known cancer, in whom the stable chronic pain is related to this cancer, ▪ Patients having received less than 30 days of treatment with strong opioids in the last three months ▪ Patients having received a level-2 analgesic at the maximum authorised dose within 48 hours prior to the inclusion visit, with an efficacy deemed to be inadequate by the investigator, ▪ Patients in whom the pain intensity has reached a score of ≥ 4 on the VAS and warranting a level-3 analgesic in the investigator's opinion, ▪ Patients with a life expectancy of more than 56 days, ▪ Patients having signed an informed consent form after having been informed of the potential benefits and risks related to inclusion in the study.
Exclusion criteria	▪ Patients with known severe liver and/or kidney failure ▪ Patients with a history of known cardiac, respiratory or neurological disease, not controlled or deemed to be incompatible with the study by the investigator, ▪ Patients with a history of allergy or hypersensitivity to fentanyl, ▪ Patients with dermatological conditions not permitting the use of a transcutaneous system or potentially affecting the absorption of fentanyl (this does not necessarily include localised lesions, which can be avoided), ▪ Patients having undergone elective surgery within a month prior to the start of treatment and/or during the 56 days of the study, ▪ Patients in a tumour growth stage warranting intravenous chemotherapy within a month prior to the start of the study and/or during the 56 days of the study, ▪ Patients with a history of drug abuse, ▪ Patients having taken part in another therapeutic study within three months prior to inclusion in the study, ▪ Pregnant or breast-feeding women, ▪ Patients who – in the investigator's opinion – are not suitable for inclusion in this clinical study or unable to meet the requirements of the study (for example, inability to rate their pain on a Visual Analogue Scale), ▪ Patients known to be HIV-positive, ▪ Patients requiring scheduled anti-tumour radiotherapy or patients having received analgesic radiotherapy within 2 weeks prior to the inclusion visit .

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Study drug	Fentanyl transdermal systems containing 25, 50, 75 and 100 μg/h
Treatment duration	56 days
Comparator	Not applicable to the study
Efficacy assessment criteria	Level of pain relief (difference between pain intensity on D0 and pain intensity on D1) on the basis of daily rating of pain intensity by the patient on a VAS. Satisfaction and quality of life (questionnaire SF36).
Tolerance assessment criteria	The incidence of constipation in the "Assessment of bowel function" questionnaire; Reporting of adverse events
Statistical methods	• Main criterion: Level of pain relief on D28: Comparison of the level of intensity on D1 and D28 using a Student test on paired series • Secondary criteria: Evolution of pain, Dosages of Fentanyl and rescue treatments used: descriptive analysis Quality of life: Comparison of mean score on D1 and D28 using a Student test on paired series

Conclusion	The aim of this trial was to assess the efficacy and tolerance of fentanyl transdermal system in patients with chronic cancer pain treated as outpatients by general practitioners under usual practice conditions. The study was discontinued before the scheduled date at the decision of the sponsor following the discovery of a number of incompletely sealed batches that were unusable. 80 patients were expected, 34 were included and 15 of these were followed-up in accordance with the duration of the protocol. Analysis of the main criterion (level of pain relief on D28), subject to the presence of a correctly completed self-assessment questionnaire, could not be performed. However, analysis of the quality of life and, particularly, of the pain score on SF36 confirms the analgesic effect of the treatment: the improvement in pain score is highly significant (p=0.0002), although the study population is very small (15 patients). It should be noted that the pain rating in the inclusion criteria used VAS > 40 on a scale of 0 to 100 mm and that the "pain" item is measured differently in the SF 36 questionnaire with standardised scores (mean 22.3 on D0 for all patients, n = 34). Improvement in the pain symptoms has positive repercussions on the patient's physical health and also makes it easier to accomplish daily activities, without necessarily improving the patient's perception of his state of health, as evidenced by the absence of improvement in scores dependent on his/her subjective assessment. 26 patients presented at least one adverse event during or following treatment, nine patients presented a serious adverse event, ten patients discontinued their treatment prematurely following an adverse event. The adverse events correspond to the effects expected with a morphine treatment. Mild to moderate constipation in 32.4% of cases, dizziness in 14.7% of cases, vomiting in 11.8% of cases, Drowsiness in 11.8% of cases. The data in the satisfaction questionnaire are highly in favour of the product; they demonstrate good compliance with treatment, a good perception relative to adverse effects and appreciation of the route of administration. They complete and confirm the data from previous studies having led to Durogesic® obtaining its marketing authorisation.

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