10 April 2013
EMA/718034/2012
Patient Health Protection

Guidance on format of the risk management plan (RMP) in the EU – in integrated format

Active substance(s) (INN or common name):	Lidocaine / Prilocaine
Pharmaco-therapeutic group (ATC Code):	ATC code: N 01 BB 20. Local amide-type anaesthetic
Name of Marketing Authorisation Holder or Applicant:	Orifarm Generics A/S
Number of medicinal products to which this RMP refers:	Choose one of the following: • 1
Product(s) concerned (brand name(s)):	Tapin

Data lock point for this RMP	22.04.2013	Version number	1.1
Date of final sign off	08.04.2014		

Part VI: Summary of activities in the risk management plan by product

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Indication: Surface anaesthesia on skin prior to needle insertion and superficial surgical intervention.

The occurrences of the listed indications are judged to be generally common.

The listed indications are not judged to be specific for any population or pattern.

VI.2.2 Summary of treatment benefits

A review of the literature shows that pre-treatment with a lidocaine/prilocaine patch is efficacious in providing dermal local anesthesia prior to venipuncture or subcutaneous injection and prior to superficial, instrumental or laser skin surgery.

Clinical studies have demonstrated that the generic product Lidocaine/Prilocaine 5% cutaneous patch produces the same cutaneous anaesthetic effect as the reference product EMLA patch® in the most common indication: local anaesthesia of intact skin prior to venipuncture.

VI.2.3 Unknowns relating to treatment benefits

None.

VI.2.4 Summary of safety concerns

No safety concerns were identified.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Tapin can be found in the Tapin's EPAR page.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

None.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable as this is an initial marketing authorisation application.