 Vital Pharma Nordic	OBRAZAC / FORM	OB-SOP-PV-007-09/01
	RMP-VP-IBU-0.1	
	Part VI: Summary of the risk management plan	

Part VI: Summary of the risk management plan

Summary of risk management plan for Ibuprofen VPN, oral suspension (ibuprofen)

This is a summary of the risk management plan (RMP) for Ibuprofen VPN, oral suspension. The RMP details important risks of Ibuprofen VPN oral suspension, how these risks can be minimised, and how more information will be obtained about Ibuprofen VPN, oral suspension's risks and uncertainties (missing information).

Ibuprofen VPN, oral suspension's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Ibuprofen VPN, oral suspension should be used.

I. The medicine and what it is used for

Ibuprofen VPN, oral suspension for the symptomatic treatment of:

- mild to moderate pain such as headache (including migraine), toothache, primary dysmenorrhea, inflammation, muscle and joint pain and fever
- symptomatic treatment of pain in arthritic diseases (e.g. rheumatoid arthritis), degenerative arthritic conditions (e.g. osteoarthritis) and in case of painful swelling and inflammation following damage to soft tissue.

Ibuprofen VPN, oral suspension contains the active substance ibuprofen in a suspension for oral use.


II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Ibuprofen VPN, oral suspension together with measures to minimise such risks and the proposed studies for learning more about the risks of Ibuprofen VPN, oral suspension are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

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II.A List of important risks and missing information

Important risks of Ibuprofen VPN, oral suspension are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Ibuprofen VPN, oral suspension. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to the information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Ibuprofen VPN, oral suspension.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Ibuprofen VPN, oral suspension.