IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0050/051/001
Case No: 2042038

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Roche Products Ltd

6 Falcon Way, Shire Park, **Welwyn Garden City**, **AL7 1TW**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Konakion 10mg Coated Tablets

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **01/04/2008**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Konakion 10 mg Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Konakion Tablet contains 10mg Phytomenadione (vitamin K_1).

Excipients: Each tablet contains 530.5mg sucrose, 75mg glucose and between 37.6mg and 41.6mg lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated tablet.
Round, off-white, sugar-coated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Konakion is indicated in the treatment of haemorrhage or threatened haemorrhage associated with a low blood level of prothrombin or factor VII. The main indications are:

As an antidote to anticoagulant drugs of the coumarin type.

4.2 Posology and method of administration

Konakion tablets are for oral administration and should be chewed or allowed to dissolve slowly in the mouth.

Adults: As an antidote to anticoagulant drugs
For potentially fatal and severe haemorrhages: Konakion intravenous injection (see separate prescribing information).

Less severe haemorrhage: Konakion is given orally in doses of 10 - 20mg
(1 to 2 tablets). The prothrombin level is estimated 8 to 12 hours later, and if the response has been inadequate, the dose should be repeated.

Lowering of prothrombin to dangerous level but no haemorrhage: A dose of 5 - 10mg Konakion orally may be given to bring the prothrombin level back to within safe limits. In such instances it is not usually necessary to discontinue the anticoagulant.

Adults: Other indications
Doses of 10 - 20mg as required.

Elderly
Elderly patients tend to be more sensitive to reversal of anticoagulation with Konakion; dosage in this group should be at the lower end of the ranges recommended.

Children
If, on the recommendation of a physician, a children's dosage is required, then it is suggested that 5 - 10mg be given.

4.3 Contraindications

Use in patients with a known hypersensitivity to any of the constituents.

4.4 Special warnings and precautions for use

Large doses of Konakion should be avoided if it is intended to continue with anticoagulant therapy.

Vitamin K_1 is not an antidote to heparin.

Konakion tablets contain glucose, sucrose and lactose (skimmed milk powder). Patients with rare galactose intolerance, Lapp lactase deficiency, fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

There is no specific evidence regarding the safety of Konakion in pregnancy but, as with most drugs, the administration during pregnancy should only occur if the benefits outweigh the risks.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

4.9 Overdose

Hypervitaminosis of vitamin K_1 is unknown.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Konakion is a synthetic preparation of vitamin K_1. The presence of vitamin K (i.e. vitamin K_1 itself or substances with vitamin K activity) is essential for the formation within the body of prothrombin, factor VII, factor IX and factor X. Lack of vitamin K leads to increased tendency to haemorrhage. When an antidote to an anticoagulant is necessary it is essential to use vitamin K_1 itself, as vitamin K analogues are much less effective.

5.2 Pharmacokinetic properties

The fat-soluble vitamin compound phytomenadione (Vitamin K_1) requires the presence of bile for its absorption from the gastro-intestinal tract. Vitamin K accumulates mainly in the liver but is stored in the body only for short periods of time. Vitamin K does not appear to cross the placenta readily and it is poorly distributed into breast milk. Phytomenadione is rapidly metabolised to more polar metabolites and is excreted in bile and urine as glucuronide and sulphate conjugates.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Silica, Colloidal Hydrated
Sucrose
Glucose Anhydrous
Skim Milk Powder
Cocoa
Theobroma Oil
Carob Bean Gum (E410)
Glycerol

Tablet Coat:
Sucrose
Rice Starch
Titanium Dioxide (E171)
Ethyl Vanillin
Acacia, Spray-Dried
Paraffin, Light Liquid
Paraffin, Hard
Talc (E553b)
Carmellose Sodium

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Keep the bottle tightly closed. Store the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

Konakion Tablets are supplied in amber glass bottles with HDPE closures and cotton-viscose pads, containing 10 coated tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Roche Products Limited
6 Falcon Way
Shire Park
Welwyn Garden City
AL7 1TW
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 50/51/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1983

Date of last renewal: 1st April 2008

10 DATE OF REVISION OF THE TEXT

April 2008