1. NAME OF THE MEDICINAL PRODUCT

Phynova Joint & Muscle Pain Relief Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains 500mg of extract (as dry extract) from **Sigesbeckia orientalis* L. subsp. *pubescens* aerial parts (equivalent to 4-5g of **Sigesbeckia orientalis* L. subsp. *pubescens* (Makino) H. Koyama).

Extraction solvent: water

For a full list of excipients see section 6.1

**Siegesbeckia pubescens* is used in the scientific literature. However the correct botanical name is as above.

3 PHARMACEUTICAL FORM

Tablet, film coated
A pale yellow oval shaped biconvex film coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the relief of backache, minor sports injuries, rheumatic or muscular pains and general aches and pains in the muscle and joints, based on traditional use only.

4.2 Posology and method of administration

Posology

Adults and elderly: Take one tablet, twice daily (one in the morning and one at night).

This product is not recommended for use in children and adolescents under 18 years of age (See ‘section 4.4 special warnings and precautions for use’).

If symptoms worsen, or do not improve after 4 weeks, a doctor or a qualified healthcare practitioner should be consulted.

Method of adminstration

For oral administration only.

Tablets should be swallowed whole with a little water or other liquid.

4.3 Contraindications

Hypersensitivity to Sigesbeckia species or any plants of the Asteraceae (Compositae) family or to any of the excipients

Pregnancy and lactation.

4.4 Special warnings and precautions for use

Do not exceed the stated dose

The use in children or adolescents under 18 years of age is not recommended because data are not sufficient and medical advice should be sought.

If the symptoms worsen, or do not improve after 4 weeks, a doctor or qualified healthcare practitioner should be consulted.

If joint pain is accompanied by swelling of the joint, redness or fever, a doctor should be consulted.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed with this product.

4.6 Fertility, pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established. In the absence of sufficient data the use during pregnancy and lactation is not recommended.

This product should not be used by women of childbearing potential unless contraception is used.

Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

None
If adverse reactions occur, a doctor or a qualified healthcare practitioner should be consulted.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No cases of overdose have been reported. Treatment should be supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

Studies on carcinogenicity and reproductive toxicity have not been performed.

In an Ames assay, *Sigesbeckia* dry extract was not mutagenic.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

Anhydrous calcium hydrogen phosphate

Microcrystalline cellulose

Magnesium stearate

Silicon dioxide

Croscarmellose sodium

Stearic acid

Film coating

Hypromellose

Titanium dioxide (E171)

Talc

Mastercote yellow (composed of Hypromellose, Yellow iron oxide (E172) and Titanium dioxide (E171)).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Blister Packs: 250µm PVDC (clear) with aluminium foil (20 µm).

Pack size: 30, 60 and 90 tablets.

Pots: Snap Secure polypropylene pot with HDPE cap (58x49mm), with 60 tablets per pot.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. Marketing Authorisation Holder

Phynova Group Ltd

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8 MARKETING AUTHORISATION NUMBER(S)

THR 41783/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/03/2020

10 DATE OF REVISION OF THE TEXT

22/10/2021