

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

POSTEON™ capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	Per capsule
<i>Persea americana</i> , <i>glycine max</i> (Avocado soybean unsaponifiables (ASU)) [Extract ratio 1:2]	300 mg
Apresflex™ <i>Boswellia serrata</i> (Indian frankincense) powder extract (gum resin)	100 mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Size 0 navy blue and white capsule with the word Posteon™ in white.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

POSTEON is a joint health supplement which supports healthy joints and helps reduce the symptoms of osteoarthritis such as joint pain and stiffness. It also helps improve joint function thus improving functional ability, range of motion and mobility.

4.2 Posology and method of administration

Adults: Take one capsule daily, or as directed by a healthcare provider.

4.3 Contraindications

Do not use POSTEON if you are hypersensitive to any of the ingredients, including excipients.

4.4 Special warnings and precautions for use

Use in children and adolescents under the age of 18 years is at the discretion of a healthcare professional. Patients allergic to banana and chestnut may have a cross allergy to this medicine.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on POSTEON. The following interactions are noted in the monographs of the active ingredients:

- Anticoagulants: ASU may increase the risk of bleeding if taken concurrently with anticoagulants such as warfarin.
- Antidepressants such as Mono-amine oxidase inhibitors (MAOI's): ASU may increase blood pressure if taken together.
- Immunosuppressant medicines: *Boswellia serrata* may alter the effects of immunosuppressive medicines.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

The effects on the ability to drive and use machines has not been studied.

4.8 Undesirable effects

Possible side effects are:

- gastrointestinal discomfort (abdominal pain, diarrhoea, heartburn, nausea, constipation.)
- headache, rash, dermatitis, drowsiness, generalized weakness.

4.9 Overdose

There is insufficient information available regarding the toxicology of *Boswellia serrata* and ASU powder.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Discipline-Specific Traditional Claims D33.7 Combination product

5.2 PHARMACOLOGICAL ACTION

Boswellia serrata gum resin extract: Clinical studies show that gum resin extracts of *Boswellia serrata* have been used traditionally to relieve symptoms of osteoarthritis. 3-O-Acetyl-11-keto-beta-boswellic acid (AKBA) is the most active compound of *Boswellia* extract and is an inhibitor of 5-lipoxygenase (5-LOX), a key enzyme in the biosynthesis of leukotrienes from arachidonic acid in the cellular inflammatory cascade

An independent randomized, double-blind, placebo-controlled clinical study conducted on subjects with osteoarthritis of the knee demonstrated relief from osteoarthritis symptoms from as early as 5 days of supplementation: reductions in pain and function scores were reported in the treatment group receiving 100mg/day of *Boswellia serrata* gum resin extract.

Avocado soy unsaponifiables (ASU) is a dietary supplement consisting of one-third avocado oil and two-thirds soybean oil. Studies have found that ASU can reduce the production/action of various joint inflammatory substances which can prevent the destruction of joint cartilage and also help in its repair.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin (bovine)
Sugar free.

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C.
Store blisters in the carton and protect from sunlight and moisture.
KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Blisters of 10 capsules each. Cartons containing 3 blisters (30 capsules)

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd
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Tel: (011) 087 0000
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8 REGISTRATION NUMBER

To be allocated
This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

June 2022