

# PROFESSIONAL INFORMATION FOR THRESHHold® JOINT SUPPORT

## COMPLEMENTARY MEDICINE

Health Supplement

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

### SCHEDULING STATUS

S0

#### 1. NAME OF THE MEDICINE

THRESHHold® JOINT SUPPORT, 1 000 mg, tablets

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Methylsulfonylmethane (OptiMSM®) 1 000 mg

Contains sugar as lactose 96 mg

For the full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Tablets

Homogeneous, white, oblong, uncoated tablets.

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

THRESHHold® JOINT SUPPORT maintains joint health by providing support for:

- Healthy joints
- Joint mobility (flexibility and movement)
- Joint comfort

##### 4.2 Posology and method of administration

###### Posology

###### Adults 18 years and older

**Maximum dosage:** 6 000 mg methylsulfonylmethane (six tablets) per day.

Do not exceed 2 000 mg methylsulfonylmethane (2 tablets) per single dose.

Take 1 000 mg methylsulfonylmethane (one tablet) to 2 000 mg methylsulfonylmethane (two tablets), two to three times a day. This may be required for 4 weeks to see beneficial effects.

###### Recommended THRESHHold® JOINT SUPPORT dosage

###### General joint support:

Two tablets per day.

###### Additional joint support:

Six tablets per day.

###### Children under 18 years of age:

Use under the medical supervision of a healthcare provider.

###### Method of administration

Take the tablets with a glass of water, preferably with meals.

##### 4.3 Contraindications

- Hypersensitivity to methylsulfonylmethane or to any of the excipients listed in section 6.1.

##### 4.4 Special warnings and precautions for use

- Not to be taken at bedtime until known how this affects the patient.

THRESHHold® JOINT SUPPORT contains lactose:

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

##### 4.5 Interaction with other medicines and other forms of interaction

None known.

##### 4.6 Fertility, pregnancy and lactation

###### Pregnancy and breastfeeding

Safety in pregnancy and breastfeeding has not been established. In the absence of sufficient data, the use of THRESHHold® JOINT SUPPORT during pregnancy and breastfeeding is not recommended unless under medical supervision.

###### Fertility

Fertility studies have not been performed.

##### 4.7 Effects on ability to drive and use machines

Based on the side effect profile, THRESHHold® JOINT SUPPORT should have no or negligible influence on the ability of the patient to drive or use machines.

It is not always possible to predict to what extent THRESHHold® JOINT SUPPORT may affect mental and/or physical ability to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which THRESHHold® JOINT SUPPORT affects them.

#### 4.8 Undesirable effects

##### Tabulated list of adverse reactions

System Organ Class	Frequency	Adverse reactions
Immune system disorders	Frequency unknown	Allergic reaction (rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing).
Gastrointestinal disorders	Frequency unknown	Nausea, diarrhoea, bloating, and stomach discomfort.

##### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>

In addition, side effects can also be reported to [info@pharmacorp.co.za](mailto:info@pharmacorp.co.za).

#### 4.9 Overdose

In an overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

Treatment of overdose should be symptomatic and supportive.

#### 5. PHARMACOLOGICAL PROPERTIES

##### 5.1 Pharmacodynamic properties

Category and class: D 34.13 Other. Complementary Medicines: Health Supplements

##### Mechanism of action

Methylsulfonylmethane (MSM) is an organo-sulphur compound naturally found in the human body. The mechanism of action has been investigated for its beneficial effect on joints, joint health, mobility and comfort.

##### 5.2 Pharmacokinetic properties

Extensive pharmacokinetic studies have not been conducted on THRESHHold® JOINT SUPPORT.

#### 6. PHARMACEUTICAL PARTICULARS

##### 6.1 List of excipients

Lactose monohydrate

Magnesium stearate (E572)

Silicon dioxide (E551)

##### 6.2 Incompatibilities

Not applicable.

##### 6.3 Shelf life

36 months.

##### 6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light and moisture.

Store in original container.

Keep the container well closed.

##### 6.5 Nature and contents of container

Round white plastic (HDPE) bottle with white plastic (PP) screw-on lid with an induction seal, containing a silica gel sachet and foam wadding, packed into an outer carton.

Pack sizes: 60 or 120 tablets.

Not all pack sizes may be marketed.

##### 6.6 Special precautions for disposal

No special requirements.

#### 7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACORP (PTY) LTD

29 Victoria Link

Route 21 Corporate Park

Irene, 0178, RSA

#### 8. REGISTRATION NUMBER(S)

To be allocated.

#### 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

#### 10. DATE OF REVISION OF THE TEXT

September 2023

THIS/PI/09.23