

**PARTICULARS TO APPEAR ON LABEL****BASE LABEL****1. NAME OF THE MEDICINAL PRODUCT**

Surgical Spirit BP  
Methyl Salicylate

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Contains: Methyl Salicylate

**3. LIST OF EXCIPIENTS**

Other ingredients: Castor Oil, Diethyl Phthalate and Industrial Methylated Spirit

**4. PHARMACEUTICAL FORM AND CONTENTS**

*Bottle:*

200 ml

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

HOW TO USE	
AGE	DOSAGE
ADULTS, ELDERLY & CHILDREN	Apply to the skin using cotton wool.

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

Keep out of the reach and sight of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

For external use only.

**8. EXPIRY DATE**

EXP

**9. SPECIAL STORAGE CONDITIONS**

Not applicable

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

Not applicable

<b>11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</b>
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Activase Pharmaceuticals Limited  
Boumpoulinas 11, 3<sup>rd</sup> Floor,  
1060 Nicosia,  
Cyprus

<b>12. MARKETING AUTHORISATION NUMBER(S)</b>
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PL 28444/0136

<b>13. BATCH NUMBER</b>
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BN

<b>14. GENERAL CLASSIFICATION FOR SUPPLY</b>
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Not applicable

<b>15. INSTRUCTIONS ON USE</b>
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Spirit for disinfecting and thorough cleansing of the skin.

Do not use this product after its 'EXP' date.

Please read the Package Leaflet on the reverse of this label before use.

<b>16. INFORMATION IN BRAILLE</b>
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Surgical Spirit BP

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **SURGICAL SPIRIT BP** (Methyl Salicylate BP 0.5% v/v)

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However, you still need to use Surgical Spirit carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Surgical Spirit is and what it is used for
2. Before you use Surgical Spirit
3. How to use Surgical Spirit
4. Possible side effects
5. How to store Surgical Spirit
6. Further information

#### **1. WHAT SURGICAL SPIRIT IS AND WHAT IT IS USED FOR**

The name of your product is Surgical Spirit BP. It contains the active ingredient called Methyl Salicylate. Surgical Spirit acts to tighten, harden and disinfect the outer layer of the skin. It is also used for general sick-room purposes.

#### **2. BEFORE YOU USE SURGICAL SPIRIT**

**Do not use Surgical Spirit solution if you** are allergic (hypersensitive) to Methyl Salicylate or any of the other ingredients.

##### **Do not apply to:**

- mucous membranes (such as the linings of the mouth and nose) or scratched or damaged skin
- broken skin

**Caution:** Flammable. Keep away from naked flames. Harmful by inhalation.

**Take special care with Surgical Spirit solution.** This product is **for external use only**.

##### **Pregnancy and Breast-feeding**

Surgical Spirit can be used during pregnancy and lactation. It is advisable to consult your doctor or pharmacist before using this product.

**Important information about some of the ingredients of Surgical Spirit:** This product contains castor oil. May cause skin reactions.

#### **3. HOW TO USE SURGICAL SPIRIT**

Follow the directions on this package leaflet or pack carefully, and ask your pharmacist to explain any part you do not understand.

**For adults, elderly and children:** Apply to the skin using cotton wool.

**If you accidentally swallow Surgical Spirit,** please consult your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Surgical Spirit may cause side-effects, although not everybody gets them.

**Serious side effects** –If any of the following happens, stop using Surgical Spirit solution and tell your doctor immediately or go to the nearest hospital emergency department:

- This product contains ethanol. Frequent use may produce irritation and dry skin.

If you notice any side-effects, consult your doctor or pharmacist.

#### **5. HOW TO STORE SURGICAL SPIRIT**

Keep out of the reach and sight of children.

Keep the bottle tightly closed.

Do not use Surgical Spirit after expiry date which is stated on the label. The expiry date refers to the last date of that month. Keep away from sources of ignition.

Surgical Spirit should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of this product no longer required. These measures will help to protect the environment.

#### **6. FURTHER INFORMATION**

##### **What Surgical Spirit contains:**

The active substance is Methyl Salicylate. The other ingredients are Castor Oil, Diethyl Phthalate, Industrial Methylated Spirit. Castor Oil prevents the skin from drying and cracking.

##### **What Surgical Spirit looks like and contents of the pack:**

Surgical spirit is a solution and comes in glass bottle with plastic caps: 100ml, 200ml, 250ml, 500ml, and 2000ml. It is also available in plastic container with plastic cap: 2000ml.

Not all pack sizes may be marketed.

##### **Marketing Authorisation Holder**

Activase Pharmaceuticals Limited, 11 Boumpoulinas, 3<sup>rd</sup> Floor, P.C. 1060, Nicosia, Cyprus.

##### **Manufacturer**

GlobeGen Laboratories Ltd., 1406 Coventry Road, South Yardley, Birmingham, B25 8AE, UK.

##### **Date of last revision**

September 2013