Public Summary

Summary for ARTG Entry: 178341 BLACKMORES FLEXAGIL PAIN RELIEF cream tube

ARTG entry for Medicine Registered
Sponsor Blackmores Ltd
Postal Address PO Box 1725, WARRIEWOOD, NSW, 2102 Australia
ARTG Start Date 13/12/2010
Product category Medicine
Status Active
Approval area Registered Complementary Medicines

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. BLACKMORES FLEXAGIL PAIN RELIEF cream tube

Product Type Single Medicine Product
Effective date 13/12/2010

Permitted Indications
No Permitted Indications included on Record

Indication Requirements
No Indication Requirements included on Record

Standard Indications
No Standard Indications included on Record

Specific Indications
- Relief of acute upper and lower back pain and improvement of impaired mobility.
- Relief/reduction of pain and swelling of, and improvement of mobility associated with, painful joint and muscle problems, contusions, distortions, sprains or other blunt injuries.
- Relieves pain, inflammation, swelling and impaired movement in sports injuries eg. ankle sprains, muscle pain.
- Relief of painful muscle tension associated with painful joint and muscle problems, contusions, strains and sprains.
- Treatment of ankle sprains/distortions including relief of pain, tenderness, swelling/oedema and improvement of mobility.
- Relief of pain of soft tissue injury and inflammation such as tenosynovitis and epicondylitis eg. tennis elbow.
- Relief of the symptoms of osteoarthritis of the knee.
- Improvement of restricted joint mobility associated with and temporary/short term relief of the pain, inflammation, swelling and stiffness of joint pain, arthritis and osteoarthritis.
- Improves physical functioning in those suffering joint pain and osteoarthritis.
- Effective alternative treatment to topical diclofenac.
- Blackmores Flexagil Pain Relief Cream is indicated for up to 7 days in reducing recent onset back, joint and muscle pain and inflammation, and the pain, tenderness, inflammation and swelling/oedema associated with acute soft tissue conditions/injuries such as sports and other blunt injuries, ankle sprains/distortions/contusions and tendonitis (tenosynovitis, epicondylitis, tennis elbow), also helping improve mobility. It may also provide temporary relief (for up to 3 weeks) in reducing symptoms including pain, swelling and stiffness associated with osteoarthritis of the knee as well as improve joint mobility and physical functioning. An effective alternative treatment to topical diclofenac.

Warnings
No Warnings included on Record

Additional Product information

Container information

<table>
<thead>
<tr>
<th>Type</th>
<th>Material</th>
<th>Life Time</th>
<th>Temperature</th>
<th>Closure</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tube</td>
<td>Al</td>
<td>3 Years</td>
<td>Store below 25 degrees Celsius</td>
<td>Neither child resistant closure nor restricted flow insert</td>
<td>Not recorded</td>
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Pack Size/Poison information

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>Poison Schedule</th>
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<tbody>
<tr>
<td>25g</td>
<td>(S5) Caution</td>
</tr>
<tr>
<td>150g</td>
<td>(S5) Caution</td>
</tr>
<tr>
<td>10g</td>
<td>(S5) Caution</td>
</tr>
<tr>
<td>50g</td>
<td>(S5) Caution</td>
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<tr>
<td>100g</td>
<td>(S5) Caution</td>
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Components

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<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Cream</th>
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<tbody>
<tr>
<td>Route of Administration</td>
<td>Topical</td>
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<tr>
<td>Visual Identification</td>
<td>Beige white cream.</td>
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<tr>
<td>Active Ingredients</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Symphytum officinale</th>
<th>350 mg/g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equivalent: Symphytum officinale (Fresh)</td>
<td>175 mg/g</td>
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</table>

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