## FEIX BIOAZUFRE / BIOSULPHUR- sulfur soap SPAI-SONS PHAMACEUTICAL INTERNATIONAL COSMETICS

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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## FEIX JABON FACIAL CON BIOAZUFRE/FACIAL SOAP WITH BIOSULPHUR

Feix solid soap, made with coconut fatty esters and sulfur bio-fluid for washing oily skin,or acne-like hyper-secretory.

Feix solid soap is ideal for washing the skin with rashes, or very sensitive to alkali and soaps made with high concentrations of lye (caustic soda).

This product must be keep out reach of the children.

This product is indicated for people who have hypersecretion of fat in the skin. It is used as a regular soap bar with the variety that this soap removes impurities from skin oils.

Feix, does not irritate or dry skin, is well tolerated at any age.

Feix biosuphur is topical application, rub the soap on the area to be treated gently massaging foam is generated.

This soap is made from a series of the ester type excipients that allow proper formation of soap, besides having ingredients that provide moisture to the skin.

IMAGE OF THE CARTON LABEL



| FEIX | <b>BIOAZUFRE / BIOSULPHUR</b> |  |
|------|-------------------------------|--|
|      |                               |  |

sulfur soap

| Product Information             |                |                    |               |  |  |
|---------------------------------|----------------|--------------------|---------------|--|--|
| Product Type                    | HUMAN OTC DRUG | Item Code (Source) | NDC:66854-002 |  |  |
| Route of Administration         | TOPICAL        |                    |               |  |  |
|                                 |                |                    |               |  |  |
| Active Ingredient/Active Moiety |                |                    |               |  |  |

| Ingredient Name                                      | <b>Basis of Strength</b> | Strength     |
|--|--------------------------|--------------|
| SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70) | SULFUR                   | 2 g in 100 g |
|  |                          |              |

|   | Ingredient <b>N</b>  | Name           |        |        | Strength     |
|---|--|----------------|--------|--------|--------------|
| SO DIUM PALM KERNI  | ELATE (UNII: 6H91L1NXTW)   |                |        |        |              |
| SO DIUM PALMITATE   | (UNII: JQ43KP6296)   |                |        |        |              |
| SODIUM STEARATE (U  | JNII: QU7E2XA9TG)  |                |        |        |              |
| SODIUM COCOYL ISE   | <b>CTHIO NATE</b> (UNII: 518 XTE8 49 3)  |                |        |        |              |
| STEARIC ACID (UNII: 4   | ELV7Z65AP)   |                |        |        |              |
| SO DIUM SARCO SINA  | <b>FE</b> (UNII: 6 EHN3PQL8Z)  |                |        |        |              |
| PARAFFIN (UNII: 1900)   | E3H2ZE)  |                |        |        |              |
| SODIUM COCOATE (U   | JNII: R1TQH25F4I)  |                |        |        |              |
| SO DIUM ISETHIO NAT   | <b>E</b> (UNII: 3R36J71C17)  |                |        |        |              |
| POLYSORBATE 80 (U   | NII: 6 O Z P 39 Z G 8 H)   |                |        |        |              |
| URTICA DIO ICA LEAF   | (UNII: X6 M0 DRN46 Q)  |                |        |        |              |
| METHYL GLUCETH-2  | <b>)</b> (UNII: J3QD0LD11P)  |                |        |        |              |
| GLYCERIN (UNII: PDC6  | A3C0OX)  |                |        |        |              |
| DIPYRITHIONE (UNII: 9   | 9L87N86R9A)  |                |        |        |              |
| HAMAMELIS VIRGINIA  | ANA LEAF (UNII: T07U1161SV)  |                |        |        |              |
| ALPHATOCOPHERC  | L ACETATE, D- (UNII: A7E6112E4N  | V)             |        |        |              |
| <b>FITANIUM DIO XIDE</b> (U   | JNII: 15FIX9V2JP)  |                |        |        |              |
| BUTYLATED HYDRO X   | <b>XYTOLUENE</b> (UNII: 1P9 D0 Z171K)  |                |        |        |              |
|   | ( /  |                |        |        |              |
|   |  |                |        |        |              |
| EDETATE DISODIUM (  | UNII: 7FLD91C86K)  |                |        |        |              |
| EDETATE DISODIUM (<br>METHYLPARABEN (UI   | UNII: 7FLD9 1C86K)<br>NII: A218C7H19T)   |                |        |        |              |
| EDETATE DISODIUM (<br>METHYLPARABEN (UI   | UNII: 7FLD9 1C86K)<br>NII: A218C7H19T)   |                |        |        |              |
| EDETATE DISODIUM (<br>METHYLPARABEN (UI   | UNII: 7FLD9 1C86K)<br>NII: A218C7H19T)   |                |        |        |              |
| EDETATE DISODIUM (<br>METHYLPARABEN (UI<br>PROPYLPARABEN (UI  | UNII: 7FLD9 1C86K)<br>NII: A218C7H19T)<br>NII: Z8IX2SC1OH)   |                |        |        |              |
| EDETATE DISODIUM (<br>METHYLPARABEN (UP<br>PROPYLPARABEN (UP<br>Product Characte  | UNII: 7FLD9 1C86K)<br>NII: A218C7H19T)<br>NII: Z8IX2SC1OH)   | Score          |        |        |              |
| EDETATE DISODIUM (<br>METHYLPARABEN (UN<br>PROPYLPARABEN (UN<br>Product Characte<br>Color   | UNII: 7FLD9 1C86K)<br>NII: A218C7H19T)<br>NII: Z81X2SC1OH)<br><b>ristics</b>                                 | Score<br>Size  |        |        |              |
| EDETATE DISODIUM (<br>METHYLPARABEN (UN<br>PROPYLPARABEN (UN<br>Product Characte<br>Color<br>Shape  | UNII: 7FLD9 1C86K)<br>NII: A218C7H19T)<br>NII: Z81X2SC1OH)<br><b>ristics</b>                                 |                | t Code |        |              |
| EDETATE DISODIUM (<br>METHYLPARABEN (UN<br>PROPYLPARABEN (UN<br>Product Characte:<br>Color<br>Shape<br>Flavor   | UNII: 7FLD9 1C86K)<br>NII: A218C7H19T)<br>NII: Z81X2SC1OH)<br><b>ristics</b>                                 | Size           | t Code |        |              |
| EDETATE DISODIUM (<br>METHYLPARABEN (UN<br>PROPYLPARABEN (UN<br>Product Characte:<br>Color<br>Shape<br>Flavor   | UNII: 7FLD9 1C86K)<br>NII: A218C7H19T)<br>NII: Z81X2SC1OH)<br><b>ristics</b>                                 | Size           | t Code |        |              |
| EDETATE DISODIUM (<br>METHYLPARABEN (UN<br>PROPYLPARABEN (UN<br>Product Characte:<br>Color<br>Shape<br>Flavor   | UNII: 7FLD9 1C86K)<br>NII: A218C7H19T)<br>NII: Z81X2SC1OH)<br><b>ristics</b>                                 | Size           | t Code |        |              |
| EDETATE DISODIUM (<br>METHYLPARABEN (UN<br>PROPYLPARABEN (UN<br>Product Characte<br>Color<br>Shape<br>Flavor<br>Contains  | UNII: 7FLD9 1C86K)<br>NII: A218C7H19T)<br>NII: Z81X2SC1OH)<br><b>ristics</b>                                 | Size           | t Code |        |              |
| EDETATE DISODIUM (<br>METHYLPARABEN (UN<br>PROPYLPARABEN (UN<br>Product Characte:<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging                                  | UNII: 7FLD9 1C86K)<br>NII: A2I8C7HI9T)<br>NII: Z8IX2SC1OH)<br>ristics<br>white (BEIGE)                       | Size<br>Imprin |        | Market | ing End Date |
| EDETATE DISODIUM (<br>METHYLPARABEN (UP<br>PROPYLPARABEN (UP<br>Product Characte<br>Color<br>Shape<br>Shape<br>Stavor<br>Contains<br>Packaging<br>I tem Code            | UNII: 7FLD9 1C86K) NII: A218C7HI9T) NII: Z8IX2SC1OH)  ristics  Package Description                           | Size           |        | Market | ing End Date |
| EDETATE DISODIUM (<br>METHYLPARABEN (UP<br>PROPYLPARABEN (UP<br>Product Characte<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging<br># Item Code                    | UNII: 7FLD9 1C86K)<br>NII: A2I8C7HI9T)<br>NII: Z8IX2SC1OH)<br>ristics<br>white (BEIGE)                       | Size<br>Imprin |        | Market | ing End Date |
| EDETATE DISODIUM (<br>METHYLPARABEN (U)<br>PROPYLPARABEN (U)<br>Product Characte<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging<br># Item Code                    | UNII: 7FLD9 1C86K) NII: A218C7HI9T) NII: Z8IX2SC1OH)  ristics  Package Description                           | Size<br>Imprin |        | Market | ing End Date |
| EDETATE DISODIUM (<br>METHYLPARABEN (UN<br>PROPYLPARABEN (UN<br>Product Characte<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging<br>I tem Code<br>NDC:66854-002-01 | UNII: 7FLD9 1C86K) NII: A218 C7H19T) NII: Z8 IX2SC1OH)  ristics  ristics Package Description 70 g in 1 BOX   | Size<br>Imprin |        | Market | ing End Date |
| EDETATE DISODIUM (<br>METHYLPARABEN (UN<br>PROPYLPARABEN (UN<br>Product Characte<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging                                   | UNII: 7FLD9 1C86K) NII: A218 C7H19 T) NII: Z8 IX2SC10H)  ristics  ristics  Package Description 70 g in 1 BOX | Size<br>Imprin |        |        | ing End Date |

Labeler - SPAI-SONS PHAMACEUTICAL INTERNATIONAL COSMETICS (880172184)

## **Registrant** - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

| Establishment                                    |         |           |                                    |  |  |  |
|--|---------|-----------|------------------------------------|--|--|--|
| Name   | Address | ID/FEI    | <b>Business Operations</b>         |  |  |  |
| SPAI-SONS PHARMACEUTICAL INTERNATIONAL COMSETICS |         | 880172184 | analysis, label, manufacture, pack |  |  |  |

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SPAI-SONS PHAMACEUTICAL INTERNATIONAL COSMETICS