PRODUCT INFORMATION

ADVANTAN® OINTMENT, FATTY OINTMENT, CREAM & LOTION

NAME OF THE MEDICINE

Advantan (methylprednisolone aceponate) 0.1% cream, ointment, fatty ointment and lotion.

The chemical name is 21-acetoxy-11β-hydroxy-6α-methyl-17-propionyloxy-1, 4-pregnadiene-3, 20-dione.

The chemical structure is

![Chemical structure of Advantan](image)

The CAS registry number is 86401-95-8. The molecular formula is C_{27}H_{36}O_{7}. The molecular weight is 472.58.

DESCRIPTION

The active ingredient of the Advantan formulations is the synthetic corticosteroid methylprednisolone aceponate (MPA), which is a white crystalline powder. Methylprednisolone aceponate is soluble in methylene chloride, acetone and ethyl acetate and is sparingly soluble in hexane and ether.

Advantan ointment is a water-in-oil emulsion containing 30% purified water. It also contains white soft paraffin, heavy liquid paraffin, white beeswax and Dehymuls E.

Advantan fatty ointment is a monophasic ointment with 96.9% hydrocarbons (white soft paraffin, heavy liquid paraffin, microcrystalline wax) and hydrogenated castor oil.

Advantan cream is an oil-in-water emulsion containing about 60% purified water. It also contains decyl oleate, glyceryl monostearate, cetostearyl alcohol, hard fat, Softisan 378, PEG-40 stearate, glyceryl 85%, butylated hydroxytoluene, benzyl alcohol, and disodium edetate.
Advantan lotion is an oil-in-water emulsion containing 68% purified water. It also contains medium chain triglycerides, caprylic/capric/stearic triglycerides, steareth-2, steareth-21, benzyl alcohol, disodium edetate and glycerol.

**PHARMACOLOGY**

**Pharmacodynamics Properties**

After topical application, Advantan (methylprednisolone aceponate) has anti-inflammatory, anti-pruritic and vasoconstrictive actions.

As for all other glucocorticoids, the mechanism of action of methylprednisolone aceponate is not completely understood. It is known that methylprednisolone aceponate binds to the intracellular glucocorticoid receptor as does the principal metabolite 6α-methylprednisolone-17-propionate, which is formed by cleavage in the skin. The steroid-receptor complex binds to certain regions of DNA, inducing anti-inflammatory, anti-pruritic and vasoconstrictive effects.

Binding of methylprednisolone aceponate or its metabolites to the steroid receptor results in the induction of lipomodulin synthesis. Lipomodulin, a protein secondary messenger (also known as lipocortin 1 and macrocortin) inhibits release of arachidonic acid, which in turn inhibits the formation of inflammatory mediators, such as prostaglandins and leukotrienes.

The immunosuppressive action of glucocorticoids can be explained in part by their inhibitory effects on chemotaxis (inhibition of leukotriene synthesis). Glucocorticoids also have anti-mitotic activity, which is not well understood.

The vasoconstrictive activity of glucocorticoids results from the inhibition of prostaglandin synthesis. Prostaglandins have vasodilatory actions. Glucocorticoids also potentiate the vasoconstrictive effect of adrenaline.

Please note that the base formulations of the various Advantan® presentations influence the therapeutic effects (see **PRESENTATION**).

**Pharmacokinetics Properties**

Methylprednisolone aceponate is bioavailable from all formulations (cream, ointment, fatty ointment and lotion). When applied topically the concentration of methylprednisolone aceponate is highest in the outer layer of the epidermis (stratum corneum) and decreases progressively in the deeper strata.

Methylprednisolone aceponate is hydrolysed in the epidermis and dermis to the principal metabolite, 6α-methylprednisolone-17-propionate. This metabolite binds to the intracellular glucocorticoid receptor with higher affinity than methylprednisolone aceponate. The binding of 6α-methylprednisolone-17-propionate to the receptor is an indicator of “bioactivation” in the skin.

Percutaneous absorption:
The degree of percutaneous absorption of methylprednisolone aceponate varies according to the state of the skin (intact/inflamed/damaged), the formulation (ointment/fatty ointment/cream/lotion) and the conditions of application (open/occlusion). Studies using the ointment, fatty ointment and cream formulations in juvenile and adult patients with neurodermatitis and psoriasis have shown that the percutaneous absorption on open application was slightly (≤2.5%) greater than the percutaneous absorption in volunteers with normal skin (0.2 – 1.5%). Occlusive dressing increased percutaneous absorption. When the superficial horny layer is removed before application of methylprednisolone aceponate, the corticoid levels in the skin are about three times higher than after application to intact skin.

Skin was artificially damaged to investigate the percutaneous absorption of methylprednisolone aceponate from the lotion formulation. Intact skin was compared with both artificially inflamed (UV-B erythema) and artificially damaged (removal of horny layer) skin. The absorption through artificially inflamed skin was very low (0.27%) and was only marginally higher than the absorption through intact skin (0.17%). The percutaneous absorption of methylprednisolone aceponate through artificially damaged skin resulted in higher levels of corticoid in the skin (15%).

Systemic absorption:
After absorption into the systemic circulation, the primary hydrolysis product of methylprednisolone aceponate, 6α-methylprednisolone-17-propionate, is rapidly conjugated with glucuronic acid, and as a result, inactivated.

The principal metabolites of methylprednisolone aceponate are eliminated primarily via the kidneys. The half-life is about 16 hours. Following intravenous administration, excretion via the urine and faeces was complete within 7 days. There is no accumulation of methylprednisolone aceponate or metabolites in the body.

The systemic effects of methylprednisolone aceponate are minimal in both man and animals following application of a topically effective dose. After treatment of large areas in patients with skin disorders, the plasma cortisol values remain within the normal range; circadian cortisol rhythm is maintained and no reduction of cortisol has been ascertained in 24-hour urine.

CLINICAL TRIALS
Topical treatment of eczema in adults using methylprednisolone aceponate 1mg/g lotion

The effectiveness of Advantan lotion and other topical corticosteroids was measured by standardised clinical assessment of signs and symptoms from which a total (sum) score for comparison was derived. The observed difference (up to 20%) in comparative sum scores is considered within norms for observer variability, and not clinically meaningful. In clinical studies, where active treatment arms were compared, the ratio of effectiveness of the two treatments did not vary by more than 20%. The statistically significant equivalence band for 95% CI of ratios was 0.8-1.25.

One double-blind, multicentre, randomised, vehicle-controlled study assessed the efficacy and safety of methylprednisolone aceponate (MPA) lotion 1mg/g applied topically twice daily in patients with eczema. The study was 14 days duration. The primary efficacy endpoint was the total score of selected objective and subjective
symptoms of eczema (erythema, oedema, vesicles, papules, weeping and itching). The mean total score at the end of treatment was statistically significant (p=0.001, one-sided) favouring MPA.

Table 1: Twice-daily administration of MPA 1mg/g lotion in adults

<table>
<thead>
<tr>
<th>Treatment administered:</th>
<th>MPA lotion (n=99)</th>
<th>Vehicle (n=48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score (mean±sd)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline:</td>
<td>14.5±3.9</td>
<td>14.6±4.2</td>
</tr>
<tr>
<td>End:</td>
<td>8.2±3.7</td>
<td>10.0±5.4</td>
</tr>
<tr>
<td>p=0.001 (one-sided)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

One double-blind, multicentre, randomised, vehicle-controlled study of 14 days duration assessed the efficacy and safety of MPA lotion 1mg/g applied twice daily versus amcinonide 0.1% lotion twice daily in patients with eczema. The primary efficacy endpoint was the total score of selected objective and subjective symptoms of eczema (erythema, oedema, vesicles, papules, weeping and itching). The mean total score at the end of treatment was statistically significant (p=0.036, one-sided) favouring MPA over placebo; MPA lotion was equivalent to amcinonide lotion (95% CI: 0.94, 1.11).

Table 2: Twice-daily administration of MPA 1mg/g lotion versus amcinonide lotion 0.1% in adults

<table>
<thead>
<tr>
<th>Treatment administered:</th>
<th>MPA lotion (n=85)</th>
<th>Amcinonide lotion (n=81)</th>
<th>Vehicle (n=51)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score (mean±sd)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline:</td>
<td>14.8±3.3</td>
<td>15.0±3.5</td>
<td>15.7±3.7</td>
</tr>
<tr>
<td>End:</td>
<td>7.5±2.4</td>
<td>7.8±2.8</td>
<td>9.1±4.3</td>
</tr>
<tr>
<td>p=0.036 (one-sided)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPA vs vehicle</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPA vs amcinonide:</td>
<td>95% CI: 0.94, 1.11</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

One double-blind, multicentre, randomised study of 14 days duration assessed the efficacy and safety of MPA lotion 1 mg/g vs betamethasone 17-valerate 0.1% lotion in patients with eczema. MPA lotion was applied either once or twice daily, whereas betamethasone was applied twice daily. The primary efficacy endpoint was total score of selected objective and subjective symptoms of eczema (erythema, oedema, vesicles, papules, weeping and itching). At the end of treatment, MPA lotion was equivalent to betamethasone lotion.

Table 3: Administration of MPA 1 mg/g lotion versus betamethasone in adults

<table>
<thead>
<tr>
<th>Treatment administered:</th>
<th>MPA lotion (OD) (n=146)</th>
<th>MPA lotion (BD) (n=94)</th>
<th>Betamethasone lotion (BD) (n=95)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score (mean±sd)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline:</td>
<td>16.1±3.9</td>
<td>15.6±3.9</td>
<td>15.7±4.1</td>
</tr>
<tr>
<td>End:</td>
<td>8.1±3.0</td>
<td>7.6±2.3</td>
<td>7.0±1.8</td>
</tr>
</tbody>
</table>
OD – once daily; BD – twice daily

One double-blind, multicentre, randomised study assessed the efficacy and safety of MPA lotion 1 mg/g versus amcinonide 0.1% lotion in patients with eczema. MPA lotion was applied either once or twice daily, whereas amcinonide was applied twice daily. The study was of 14 days duration. The primary efficacy endpoint was the total score of selected objective and subjective symptoms of eczema (erythema, oedema, vesicles, papules, weeping and itching). At the end of treatment, MPA lotion was equivalent to amcinonide lotion.

Table 4: Administration of MPA 1mg/g lotion versus amcinonide lotion 0.1% in adults

<table>
<thead>
<tr>
<th>Treatment administered:</th>
<th>MPA lotion (OD) (n=122)</th>
<th>MPA lotion (BD) (n=82)</th>
<th>Amcinonide lotion (BD) (n=83)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results:</td>
<td>Baseline:</td>
<td>End:</td>
<td></td>
</tr>
<tr>
<td>Total score (mean±sd)</td>
<td>15.0±4.1</td>
<td>14.9±4.4</td>
<td>15.7±4.1</td>
</tr>
<tr>
<td></td>
<td>7.4±1.9</td>
<td>7.3±2.7</td>
<td>7.4±2.2</td>
</tr>
<tr>
<td>MPA OD vs MPA BD:</td>
<td>95% CI: 0.93, 1.10</td>
<td>95% CI: 0.95, 1.14</td>
<td>95% CI: 0.97, 1.15</td>
</tr>
</tbody>
</table>

Topical treatment of eczema in children using methylprednisolone aceponate 1mg/g lotion

One double-blind, multicentre, randomised study assessed the efficacy and safety of MPA lotion 1 mg/g versus hydrocortisone 17-butyrate 0.1% lotion in paediatric patients with eczema. MPA lotion was applied once daily, and hydrocortisone 17-butyrate was applied twice daily. The study was of 14 days duration. The primary efficacy endpoint was the total score of selected objective and subjective symptoms of eczema (erythema, oedema, vesicles, papules, weeping and itching).

At the end of treatment MPA lotion was equivalent to hydrocortisone 17-butyrate lotion (MPA vs hydrocortisone 17-butyrate: 95% CI: 0.88, 1.09).

Table 5: Administration of MPA 1 mg/g lotion versus hydrocortisone 17-butyrate lotion 0.1% in children

<table>
<thead>
<tr>
<th>Treatment administered:</th>
<th>MPA lotion (OD) (n=72)</th>
<th>Hydrocortisone 17 – butyrate (BD) (n=73)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results:</td>
<td>Baseline:</td>
<td></td>
</tr>
<tr>
<td>Total score (mean±sd)</td>
<td>16.5±3.6</td>
<td>16.0±3.4</td>
</tr>
<tr>
<td></td>
<td>7.6±2.7</td>
<td>7.4±2.1</td>
</tr>
<tr>
<td>95% CI: 0.88, 1.09</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
INDICATIONS

Advantan cream, ointment and fatty ointment are indicated for the topical treatment of eczema and psoriasis in adults and children.

Advantan lotion is indicated for the topical treatment of eczema in adults and children.

CONTRAINDICATIONS

Advantan is contraindicated in viral diseases (e.g. vaccinia, varicella/herpes zoster) and when tuberculous or syphilitic processes and post-vaccination skin reactions are present in the area to be treated. If rosacea, ulcera, atrophic skin diseases, acne vulgaris or perioral dermatitis are present, Advantan must not be applied to the face.

Hypersensitivity to methylprednisolone aceponate or any component of the formulations.

Children under four months due to lack of experience.

PRECAUTIONS

FOR EXTERNAL USE ONLY.

Advantan should not be allowed to come into contact with deep open wounds, muscosae or the eyes when being applied to the face.

Additional specific therapy is required in skin conditions infected with bacteria and/or fungi. Any spread of infection requires withdrawal of topical corticosteroid therapy.

If the skin dries out excessively under protracted use of Advantan® cream or lotion, a change should be made to one of the formulations with a higher fat content (Advantan® ointment or fatty ointment).

If signs of hypersensitivity develop, Advantan® should be discontinued and appropriate treatment instituted.

Any of the side effects that have been reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

As known from systemically administered corticosteroids, glaucoma may also develop from using topical corticosteroids (eg. after large-dose or extensive application over a prolonged period, application under occlusive dressings, or application to skin around or near the eyes).

Advantan is a potent steroid formulated for topical application. As with all potent corticosteroids, the possibility of hypothalamic-pituitary-adrenal (HPA) axis suppression resulting from percutaneous absorption of methylprednisolone must be considered when initiating or reviewing therapy, as adequate studies are not available to define the degree of risk.
Treatment of large areas has been noted to produce some suppression of cortisol secretion, but plasma levels remain above the lower limit of the normal range and circadian rhythm is maintained. Nevertheless, when treating large areas the duration of use should be kept as brief as possible. Extensive application of topical corticosteroids to large areas of the body or for prolonged periods of time, in particular under occlusion, significantly increases the risk of side effects. This is particularly important in children who may absorb proportionately larger amounts of topical corticosteroid and thus be more susceptible to systemic toxicity.

Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated. In infants and children, plastic pants and napkins may act as occlusive dressings and increase absorption. Because of children’s larger skin surface area to bodyweight ratio, paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing’s syndrome than adults. Chronic/long-term corticosteroid therapy may interfere with growth and development of children. Use of topical corticosteroids in children should be limited to the least amount required for therapeutic effect.

Local atrophy, telangiectasia and striae may occur after prolonged treatment or excessive application. Treatment should be discontinued if symptoms such as cutaneous atrophy occur (see also ADVERSE EFFECTS).

There was no sensitising effect or potential in animal studies.

Two excipients contained in Advantan cream (cetostearyl alcohol and butyl hydroxytoluene) may cause local skin reactions (e.g. contact dermatitis). Butyl hydroxytoluene may also cause irritation in the eyes and mucous membranes.

**Carcinogenicity/Mutagenicity**

Animal studies to evaluate the carcinogenic potential of methylprednisolone aceponate have not been conducted. Other glucocorticoid drugs have been shown to cause hepatic tumours in rats, and it must be assumed that methylprednisolone aceponate would have similar activity. However, in humans epidemiological surveys of many years of systemic glucocorticoid therapy have not revealed any evidence for a tumourigenic action of this substance class.

Methylprednisolone aceponate did not elicit any genotoxic effects or chromosomal damage in *in vitro* and *in vivo* assays conducted in bacteria and mammalian cells.

**Use in Pregnancy**

Pregnancy – Category C

There are no adequate data from the use of Advantan cream, ointment and fatty ointment in pregnant women.

Animal studies with methylprednisolone aceponate have shown embryolethal effects in rats dosed subcutaneously during the period of organogenesis at doses greater than 1
mg/kg/day and in rabbits following dermal application at doses greater than 0.25 mg/kg/day. No teratogenic effects were observed in rabbits, but in rats the incidence of ventricular septal defects and of cleft palate were increased at subcutaneous doses greater than 1 and 10 mg/kg/day. Epidemiological studies suggest that there could possibly be an increased risk of oral clefts among newborns or women who were treated with glucocorticosteroids during the first trimester of pregnancy. In general, the use of topical preparations containing corticoids should be avoided during the first trimester of pregnancy.

Reduced placental and birth weight have been recorded in animals and humans after long-term treatment. Since the possibility of suppression of the adrenal cortex in the newborn baby after long-term treatment must be considered, the needs of the mother must be carefully weighed against the risk to the foetus when prescribing these drugs. Maternal pulmonary oedema has been reported, with tocolysis and fluid overload.

The clinical indication for treatment with methylprednisolone aceponate must be carefully reviewed and the benefits weighed against the risks in pregnant and lactating women. Treatment of large areas or prolonged use (greater than 4 weeks) must be avoided.

Use in lactation

It is not known whether methylprednisolone aceponate is secreted in breast milk. Methylprednisolone aceponate should be used during lactation only if benefits outweigh the risks.

Nursing mothers should avoid treatment over large areas, prolonged use or occlusive dressings. Advantan should not be applied to the chest area during breast feeding to avoid possible ingestion by infants.

When considering use during lactation, note that after systemic administration, very small amounts of glucocorticoid may be present in breast milk. There is only a slight risk of exposure to methylprednisolone aceponate in breast milk following maternal dermal application at therapeutic doses, because the systemic absorption of methylprednisolone aceponate is minimal.

INTERACTION WITH OTHER MEDICINES

No specific information exists on interactions with other medications.

ADVERSE EFFECTS

In clinical studies, most frequently observed side-effects included application site burning and application site pruritus with Advantan cream and ointment. For Advantan fatty ointment, application site folliculitis and application site burning were observed most frequently.

Frequencies of side-effects observed in clinical studies and given in the table below are defined according to the MedDRA frequency convention: very common (>1/10); common (>1/100, <1/10); uncommon (>1/1,000; <1/100), rare (>1/10,000, <1/1,000);
very rare (<1/10,000), not known (cannot be estimated from available data). MedDRA version 12.0 was used for coding.

**Advantan Cream 0.1%**

<table>
<thead>
<tr>
<th>System organ class</th>
<th>common</th>
<th>uncommon</th>
<th>rare</th>
</tr>
</thead>
<tbody>
<tr>
<td>General disorders and administration site reaction</td>
<td>application site burning, application site pruritus</td>
<td>application site dryness, application site erythema, application site vesicles, application site folliculitis, application site rash, application site paraesthesia</td>
<td>application site cellulitis, application site edema, application site irritation</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td></td>
<td>drug hypersensitivity</td>
<td></td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td></td>
<td></td>
<td>pyoderma, skin fissures, telangiectasia, skin atrophy, fungal skin infection, acne</td>
</tr>
</tbody>
</table>

**Advantan Ointment 0.1%**

<table>
<thead>
<tr>
<th>System organ class</th>
<th>common</th>
<th>uncommon</th>
<th>not known (cannot be estimated from available data)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General disorders and administration site reaction</td>
<td>application site burning, application site pruritus</td>
<td>application site dryness, application site erythema, application site vesicles, application site rash, application site paraesthesia</td>
<td></td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td></td>
<td>skin atrophy, ecchymosis, impetigo, skin greasy</td>
<td>acne</td>
</tr>
</tbody>
</table>
• Advantan Fatty Ointment 0.1%

<table>
<thead>
<tr>
<th>System organ class</th>
<th>common</th>
<th>uncommon</th>
<th>not known (cannot be estimated from available data)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>application site folliculitis, application site burning</td>
<td>application site pustules, application site vesicles, application site pruritus, application site pain, application site erythema, application site papules</td>
<td></td>
</tr>
<tr>
<td>General disorders and administration site reaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>skin fissures, telangiectasia</td>
<td>acne</td>
<td></td>
</tr>
</tbody>
</table>

As with other corticoids for topical application, the following local side effects may occur: skin atrophy, skin striae, application folliculitis, hypertrichosis, telangiectasia, perioral dermatitis, skin discolouration, and hypersensitivity to any of the ingredients of the formulations. Systemic effects due to absorption may occur when topical preparations containing corticoids are applied.

**DOSAGE AND ADMINISTRATION**

Advantan is FOR EXTERNAL TOPICAL USE ONLY and NOT FOR OPHTHALMIC USE.

The Advantan formulation most appropriate to the skin condition should be used.

If the skin dries out excessively during treatment with Advantan cream or lotion, a change should be made to one of the formulations with a higher fat content ie. Advantan ointment or fatty ointment.

**Advantan ointment, fatty ointment & cream**
Advantan ointment, fatty ointment or cream should usually be applied as a thin coating once per day to the affected areas. In the treatment of psoriasis, twice daily application may be required.

The duration of use should be less than 12 weeks in adults and less than 4 weeks in children.

**Advantan lotion**
Advantan lotion should be applied sparingly once daily to the affected areas and rubbed in gently.
The duration of use should be less than 12 weeks in adults and less than 4 weeks in children.

**OVERDOSAGE**

Excessive dosing may occur with prolonged or intensive topical use. Refer to **ADVERSE EFFECTS** for further information.

Acute toxicity studies with methylprednisolone aceponate (namely oral ingestion, or single dermal application to a large area, under conditions favourable to absorption) do not indicate that any acute intoxication is expected.

Contact the Poisons Information Centre on 131 126 for further advice on overdosage management.

**PRESENTATION AND STORAGE CONDITIONS**

**Presentation**

Advantan formulations contain 0.1% methylprednisolone aceponate.

**Advantan ointment**
Skin conditions which are neither weeping nor very dry require a base with balanced proportions of fat and water. Advantan ointment is suitable for dry, fissured, scaly or hyperkeratinised skin areas. It should not be used in areas such as the axilla, groin or skin folds. Advantan ointment makes the skin slightly greasy without retaining warmth and fluid. It is available in tubes of 5g, 10g, 15g, 30g, 50g or 100g.

**Advantan fatty ointment**
Very dry skin and the chronic stage of skin conditions require an anhydrous base. Advantan fatty ointment base has an occlusive effect. It is suitable for treatment of areas where the stratum corneum is particularly thick, such as the pressure areas of elbows, knees, palms and soles. It is available in tubes of 5g, 10g, 15g, 30g, 50g or 100g.

**Advantan cream**
As a low-fat formulation with a high water content, Advantan cream is suitable for acute and subacute weeping stages of eczema, for very greasy skin and for use on exposed or hirsute areas. It is available in tubes of 5g, 10g, 15g, 30g, 50g or 100g.

**Advantan lotion**
Advantan lotion’s formulation confers cooling properties. It is intended primarily for the treatment of acute eczema, where acute inflammation and tenderness is present. Because it is the least occlusive of the Advantan formulations, it is suitable for treatment of large areas and skin flexures, as well as hirsute regions. It is available in tubes of 20g or 50g.
Storage Conditions

Advantan ointment or cream: Store below 25°C.
Advantan fatty ointment or lotion: Store below 30°C.

When stored below 25°C, Advantan ointment, cream and lotion are stable for 3 years from date of manufacture.

When stored below 30°C, Advantan fatty ointment is stable for 5 years from date of manufacture.

Do not use beyond the expiry date on the package.

Do not use if the pack shows signs of damage or tampering.

NAME AND ADDRESS OF THE SPONSOR

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073
Australia

POISON SCHEDULE OF THE MEDICINE
PRESCRIPTION ONLY MEDICINE

DATE OF FIRST INCLUSION IN THE ARTG

11 July 1994

Date of most recent amendment: 17 March 2015

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