Local Product Document

Generic Name: Crisaborole
Trade Name: STAQUIS®
CDS Effective Date: May 26, 2022
Supersedes: NA

1. NAME OF THE MEDICINAL PRODUCT

STAQUIS 2% (20 mg/g) ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The medicinal product contains 2% crisaborole (w/w) in an ointment.

One gram of ointment contains 20 mg of crisaborole.

Excipients with known effect:
This medicine contains 90 mg propylene glycol in each gram of ointment.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White to off-white ointment.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

STAQUIS is indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

4.2. Posology and method of administration

Posology

Adults
A layer of ointment is to be applied twice daily to affected areas for management of active disease.

For maintenance, once affected areas are clear or almost clear, a layer of ointment is to be applied once daily to the most commonly affected areas. If signs and symptoms of the disease worsen, a layer of ointment is to be applied twice daily to affected areas.

STAQUIS can be used on all skin areas, including the face, neck, and intertriginous areas. The use of STAQUIS on the scalp has not been studied.

Pediatric population
For children and adolescents (2 years to 17 years of age) the posology is the same as for adults.

Special populations
Clinical trials with hepatic or renal impaired subjects have not been conducted. However, dosage adjustment is not expected to be necessary in subjects with mild to moderate hepatic impairment or in subjects with renal impairment.

Clinical studies of STAQUIS did not include sufficient numbers of subjects 65 years of age and over to determine whether they respond differently from younger subjects. However, dosage adjustment is not expected to be necessary in this patient population.

Method of administration
STAQUIS is for topical use only and not for oral, ophthalmic, or intravaginal use.

STAQUIS has not been studied under occlusion. However, clinical experience available for use of the ointment under occlusion (i.e., diapers/nappies or clothing) has not shown the necessity for any dosage adjustment.

Patients should be instructed to wash their hands after applying STAQUIS, unless it is their hands that are being treated. If someone else applies STAQUIS to the patient, they too should wash their hands after application.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4. Special warnings and precautions for use

STAQUIS is not for oral, ophthalmic, or intravaginal use. In cases of accidental exposure in the eyes or mucous membranes, the ointment should be thoroughly wiped off and/or rinsed with water.

Hypersensitivity
Hypersensitivity, including contact urticaria, has occurred in patients treated with STAQUIS. Hypersensitivity should be suspected in the event of severe pruritus, swelling and erythema at the application site or at a distant site. If signs and symptoms of hypersensitivity occur, discontinue STAQUIS immediately and initiate appropriate therapy.

4.5. Interaction with other medicinal products and other forms of interaction

Neither crisaborole nor its 2 main metabolites are expected to cause drug interactions by induction or inhibition of cytochrome P450 (CYP) enzymes based on *in vitro* and *in vivo* data (see section 5.2).

One of the 2 metabolites showed moderate inhibition of uridine diphosphate (UDP)-glucuronosyltransferase (UGT) 1A9 and may result in a moderate increase in the concentrations of sensitive UGT1A9 substrates (see section 5.2).

STAQUIS has not been evaluated in combination with other cutaneous medicinal products used to treat mild to moderate atopic dermatitis and co-application on the same skin areas is not recommended. Emollients may be used on other areas of skin not affected by atopic dermatitis; co-application of emollients with Staquis on the same skin areas is not recommended.

4.6. Fertility, pregnancy and lactation

Pregnancy
There is a limited amount of data from the use of STAQUIS in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity at maternally non-toxic doses (see section 5.3). Because animal reproduction studies are not always predictive of the human response, as a precautionary measure, the mother's clinical benefit of STAQUIS along with any potential risk on the fetus should be considered.

Breast-feeding
Animal studies on milk excretion after topical application were not conducted and the use of STAQUIS in breast-feeding women has not been studied. STAQUIS is systemically absorbed. It is unknown whether crisaborole or its metabolites or excipients are excreted in human milk following topical application of STAQUIS or the effects of the medicinal product on the breastfed infant or on human milk production. The lack of clinical data during lactation precludes a clear determination of the risk of STAQUIS to a breastfed infant. Therefore, the developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for STAQUIS and any potential adverse effects on the breastfed infant from STAQUIS or from the underlying maternal condition.

To avoid unintentional ingestion by the newborn, STAQUIS should not be applied to the breast.

Fertility
Reproduction studies in male or female rats using oral administration of crisaborole revealed no effects on fertility (see section 5.3).

4.7. Effects on ability to drive and use machines

No studies with STAQUIS on the effect of the ability to drive or use machines have been performed, therefore STAQUIS has no known influence on the ability to drive or use machines.

4.8. Undesirable effects

The most common adverse drug reactions from completed STAQUIS clinical trials (Trials 1 and 2) were application site reactions (5.6% and 3.6% for STAQUIS and vehicle groups, respectively) and most were classified as mild. Of these drug-related application site reactions, application site pain (e.g., burning or stinging) was the only adverse drug reaction that showed a clinically relevant difference in rates between the treatment groups (4.4% and 1.2% for STAQUIS and vehicle groups, respectively). Generally, application site pain was noted early in the treatment period and was transient in nature, resolving spontaneously.

Table 1: Adverse Drug Reactions (ADRs) by System Organ Class (SOC) and Counsil for International Organizations of Medical Science (CIOMS) Frequency Category Listed in Order of Decreasing Medical Seriousness or Clinical Importance Within Each Frequency Category and SOC.

System Organ Class	Very Common ≥ 1/10	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1,000 to < 1/100	Rare ≥ 1/10,000 to < 1/1,000	Very Rare < 1/10,000	Frequency not known (cannot be estimated from the available data)
General disorders and administration site conditions		Application site reactions (e.g., application site pain*, application site pruritus)				

* Refers to skin sensations such as burning or stinging

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Pusat Farmakovigilans/ MESO Nasional Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika,

Psikotropika, Prekursor dan Zat Adiktif Badan Pengawas Obat dan Makanan https://e-meso.pom.go.id/ADR.

4.9. Overdose

There has been no experience of overdose with STAQUIS. Overdose following topical administration is unlikely. If too much STAQUIS has been applied, the excess can be wiped off.

STAQUIS is not for oral use. Oral ingestion may lead to adverse effects associated with systemic administration. If oral ingestion occurs, medical advice should be sought.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Mechanism of action
Crisaborole is an anti-inflammatory benzoxaborole phosphodiesterase-4 (PDE4) inhibitor that suppresses the secretion of certain cytokines, such as tumor necrosis factor-α (TNF-α), interleukins (IL-2, IL-4, IL-5), and interferon gamma (IFNγ), and improves skin barrier function as measured by transepidermal water loss (TEWL). Crisaborole applied on atopic dermatitis lesions of patients reduces expression of atopic inflammation associated chemokines including CCL17, CCL18, and CCL22.

Clinical efficacy
Two multicenter, randomized, double-blind, parallel-group, vehicle-controlled trials (Trials 1 and 2), which were identical in design, included a total of 1,522 subjects 2 to 79 years of age (86.3% of subjects were 2 to 17 years of age) with a 5% to 95% treatable body surface area (BSA). At baseline (pooled study data), 38.5% of the subjects had an Investigator's Static Global Assessment (ISGA) of mild (2), and 61.5% had an ISGA of moderate (3), in the overall assessment of atopic dermatitis (erythema, induration/papulation, and oozing/crusting) on a severity scale of 0 to 4.

In both trials, subjects were randomized 2:1 to receive STAQUIS or vehicle applied twice daily for 28 days. The primary efficacy endpoint was the proportion of subjects at Day 29 who achieved an ISGA of clear (0) or almost clear (1) with at least a 2-grade improvement from baseline, comparing twice daily STAQUIS-treated subjects to vehicle-treated subjects. In both trials, a statistically significantly greater percentage of subjects achieved this endpoint in the STAQUIS-treated group compared with the vehicle-treated group.

The secondary efficacy endpoints were the proportion of subjects at Day 29 with an ISGA of clear or almost clear and the time to achieve an ISGA of clear or almost clear with at least a 2-grade improvement from baseline. The proportion of subjects achieving an ISGA of clear or almost clear at Day 29 in the twice daily STAQUIS-treated group compared to the twice daily vehicle-treated group was statistically significantly higher. Twice daily STAQUIS-treated subjects showed a statistically significantly shorter time to achieve an ISGA of clear or almost

clear with at least a 2-grade improvement from baseline than vehicle-treated subjects by the log-rank test for each study.

Efficacy results from the two trials are summarized in Table 2.

Table 2: Efficacy Outcomes in Subjects with Mild to Moderate Atopic Dermatitis at Day 29

	Trial 1		Trial 2	
	STAQUIS Twice Daily (N=503)	**Vehicle Twice Daily (N=256)**	**STAQUIS Twice Daily (N=513)**	**Vehicle Twice Daily (N=250)**
ISGA[a]	32.8%	25.4%	31.4%	18.0%
p-value	0.038[b]		<0.001[b]	
ISGA of clear or almost clear[c]	51.7%	40.6%	48.5%	29.7%
p-value	0.005[d]		<0.001[d]	
Time to ISGA[a,e]	NC[f]	NC[f]	NC[f]	NC[f]
p-value	<0.001[g]		<0.001[g]	

[a] Defined as an ISGA of clear or almost clear with at least a 2-grade improvement from baseline.
[b] p-value from a logistic regression (with Firth option) test with factors of treatment group and analysis center. Trial 1 estimates from logistic regression are 29.1% and 22.0% for STAQUIS and vehicle, respectively. Trial 2 estimates from logistic regression are 26.5% and 14.2% for STAQUIS and vehicle, respectively. Values were adjusted for multiple imputation.
[c] At least a 2-grade improvement from baseline was not required.
[d] p-value from a logistic regression (with Firth option) test with factors of treatment group and analysis center. Trial 1 estimates from logistic regression are 49.0% and 37.7% for STAQUIS and vehicle, respectively. Trial 2 estimates from logistic regression are 45.2% and 25.5% for STAQUIS and vehicle, respectively. Values were adjusted for multiple imputation.
[e] Medians computed using Kaplan-Meier methods.
[f] The median time to achieve an ISGA of clear or almost clear with at least a 2-grade improvement from baseline could not be calculated (NC), as fewer than 50% of subjects achieved an ISGA of clear or almost clear with at least a 2-grade improvement from baseline.
[g] p-value from log-rank test.

In both clinical trials (Trial 1 and 2), the signs (erythema, induration/papulation, exudation, excoriation, and lichenification) and a symptom (pruritus) of atopic dermatitis were assessed.

The proportion of subjects with improvement in signs of atopic dermatitis (defined as None [0] or Mild [1] with at least a 1-grade improvement from baseline on a 4-point scale) at Day 29 was greater in twice daily STAQUIS-treated subjects than twice daily vehicle-treated subjects for all 5 clinical signs of atopic dermatitis. In Trial 2, all 5 clinical signs of atopic dermatitis were statistically significantly improved. In Trial 1, statistical significance was achieved for erythema, exudation, and excoriation. Results for each trial are summarized in Table 3.

Table 3: Proportion of Subjects Achieving Improvement[a] in Signs of Atopic Dermatitis at Day 29

	Trial 1			Trial 2		
	STAQUIS Twice Daily (N=503)	**Vehicle Twice Daily (N=256)**	**p-value[b]**	**STAQUIS Twice Daily (N=513)**	**Vehicle Twice Daily (N=250)**	**p-value[b]**
Erythema	62.8%	46.1%	<0.001	54.9%	33.9%	<0.001
Induration/Papulation	57.7%	54.8%	0.375	51.9%	40.2%	0.005
Exudation	41.0%	33.3%	0.027	38.1%	27.2%	0.004
Excoriation	63.0%	51.8%	0.004	57.2%	44.2%	0.001
Lichenification	51.7%	46.5%	0.128	51.4%	35.3%	<0.001

[a] Defined as None or Mild with at least a 1-grade improvement from baseline.
[b] p-value from Cochran-Mantel-Haenszel (CMH) test stratified by analysis center.

The proportion of subjects achieving improvement in pruritus, defined as achieving a weekly mean Severity of Pruritus Scale (SPS) score of ≤1 with at least a 1-point improvement from baseline on a severity scale of 0 to 3, was assessed at each scheduled study visit. A statistically significantly higher proportion of subjects achieving improvement in pruritus was observed with twice daily STAQUIS-treated subjects compared to twice daily vehicle-treated subjects at Week 4, as summarized in Table 4.

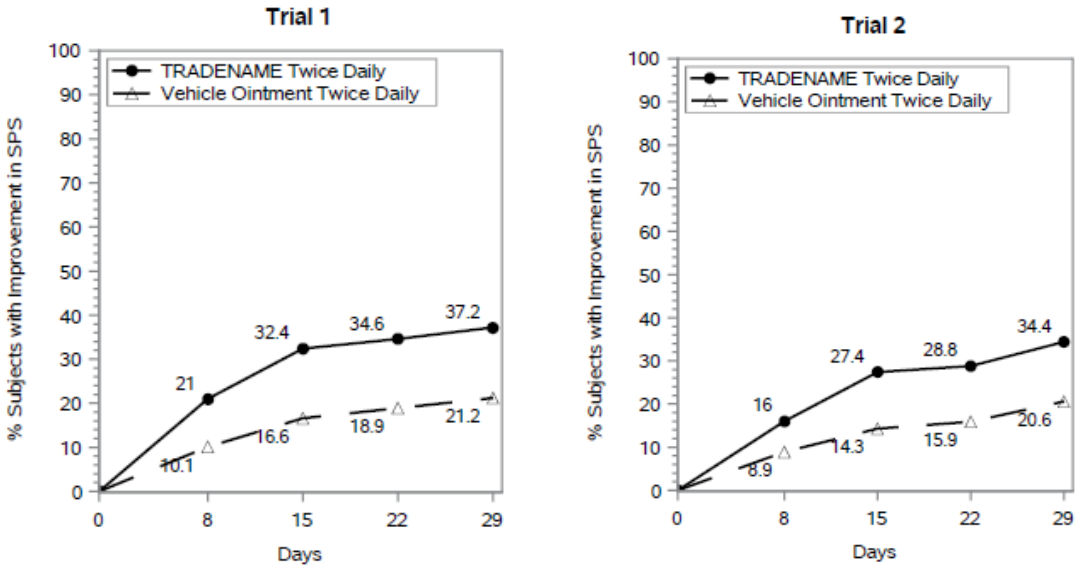
Table 4: Improvement in the Severity of Pruritus Scale (SPS) in Subjects with Mild to Moderate Atopic Dermatitis at Week 4

	Trial 1			Trial 2		
	STAQUIS Twice Daily (N=363)	**Vehicle Twice Daily (N=170)**	**p-value**	**STAQUIS Twice Daily (N=363)**	**Vehicle Twice Daily (N=165)**	**p-value**
Improvement in SPS	37.2%	21.2%	p<0.001	34.4%	20.6%	p<0.001

Improvement in SPS is defined as achieving a weekly mean Severity of Pruritus Scale (SPS) score of ≤1 with at least a 1-point improvement from baseline.

The pruritus improvement rates over time are presented in Figure 1.

Figure 1: Improvement in SPS Over Time in Subjects with Mild to Moderate Atopic Dermatitis[28]



Improvement in SPS is defined as achieving a weekly mean Severity of Pruritus Scale (SPS) score of ≤1 with at least a 1-point improvement from baseline.

The time to improvement in pruritus was defined as time to achieve a daily mean SPS score of ≤1 with at least a 1-point improvement from baseline. In Trial 1 and Trial 2, twice daily STAQUIS-treated subjects had a statistically significant shorter median time to improvement than vehicle-treated subjects. In Trial 1, twice daily STAQUIS-treated subjects achieved improvement in pruritus symptoms with a median of 4 days versus 9 days for twice daily vehicle-treated subjects (p=0.0008). In Trial 2, twice daily STAQUIS-treated subjects achieved improvement in pruritus symptoms with a median of 5 days versus 9 days for twice daily vehicle-treated subjects (p=0.0042).

In the pooled clinical trials (Trial 1 and 2), the twice daily STAQUIS-treated group showed a greater reduction in mean treatable percent BSA affected with atopic dermatitis (-7.4% from a baseline of 18.3%) than the twice daily vehicle-treated group (-4.4% from a baseline of 18.1%) at Day 29.

5.2. Pharmacokinetic properties

Absorption

The pharmacokinetics (PK) of STAQUIS were investigated in 33 pediatric subjects 2 to 17 years of age with mild to moderate atopic dermatitis and a mean ± standard deviation (SD) BSA involvement of 49 ± 20% (range 27% to 92%). In this study, subjects applied approximately 3 mg/cm^2 of STAQUIS ointment (dose range was approximately 6 g to 30 g per application) twice daily for 8 days. Plasma concentrations were quantifiable in all subjects. The mean ± SD maximum plasma concentration (C_{max}) and area under the concentration time curve from 0 to 12

hours post dose (AUC_{0-12}) for crisaborole on Day 8 were 127 ± 196 ng/mL and 949 ± 1240 ng*h/mL, respectively. Systemic concentrations of crisaborole were at steady state by Day 8. Based on the ratios of AUC_{0-12} between Day 8 and Day 1, the mean accumulation factor for crisaborole was 1.9. Systemic levels of crisaborole and its main metabolites were similar between age cohorts of 2 to 5 years, 6 to 11 years, and 12 to 17 years.

Distribution

Based on an *in vitro* study, crisaborole is 97% bound to human plasma proteins.

Biotransformation and elimination

Crisaborole is substantially metabolised into inactive metabolites. The main metabolite 5-(4-cyanophenoxy)-2-hydroxyl benzylalcohol (metabolite 1), is formed via multiple CYP enzymes including CYP3A4, 1A2 and hydrolysis; this metabolite is further metabolised into downstream metabolites, among which 5-(4-cyanophenoxy)-2-hydroxyl benzoic acid (metabolite 2), formed via oxidation, is also a main metabolite. PK of metabolites 1 and 2 were assessed in the PK study described above and the systemic concentrations were at or near steady state by Day 8. Based on the ratios of AUC_{0-12} between Day 8 and Day 1, the mean accumulation factors for metabolites 1 and 2 were 1.7 and 6.3, respectively. The mean ± SD C_{max} and AUC_{0-12} for metabolite 2 on Day 8 were 1850 ± 1830 ng/mL and 18200 ± 18100 ng*h/mL, respectively. Renal excretion of metabolites is the major route of elimination. Approximately 25% of the radiolabelled dose was absorbed and predominantly excreted in the urine.

Drug interactions

Potential for crisaborole to influence the PK of other drugs

In vitro studies using human liver microsomes indicated that under the conditions of clinical use, crisaborole and metabolite 1 are not expected to inhibit CYP1A2, 2B6, 2C8, 2C9, 2C19, and 3A4.

In vitro human liver microsomes studies for metabolite 2 showed that it did not inhibit activities of CYP2C19, 2D6, and 3A4; was a weak inhibitor of CYP1A2 and 2B6; and a moderate inhibitor of CYP2C8 and 2C9. The most sensitive enzyme, CYP2C9, was further investigated in a clinical trial using warfarin as a CYP2C9 substrate. The results of this study showed no drug interaction potential.

In vitro studies indicate that under the condition of clinical use, crisaborole and metabolites 1 and 2 are not expected to induce CYP enzymes.

Based on *in vitro* data, crisaborole is metabolised to some extent (<30%) via CYP3A4 and CYP1A2. Concomitant administration of Staquis and potent CYP3A4 or CYP1A2 inhibitors may result in increases in crisaborole systemic exposure.

In vitro studies showed that crisaborole and metabolite 1 did not inhibit the activities of uridine diphosphate (UDP)-glucuronosyltransferase (UGT) 1A1, 1A4, 1A6, 1A9, 2B7, and 2B15. Metabolite 2 did not inhibit UGT1A4, 1A6, 2B7, and 2B15. Metabolite 2 showed weak inhibition of UGT1A1, however, no clinically significant drug interactions are expected between

crisaborole (and its metabolites) and UGT1A1 substrates at therapeutic concentrations. Metabolite 2 showed moderate inhibition of UGT1A9 and may result in a moderate increase of the concentrations of sensitive UGT1A9 substrates, such as propofol. A clinically relevant interaction between metabolite 2 and propofol is not anticipated due to the posology and method of administration of propofol (intravenous infusion or injection with titration to clinical effect for anaesthesia or sedation). Drug interaction studies with sensitive UGT1A9 substrates have not been conducted.

In vitro studies indicate that under the condition of clinical use, crisaborole and metabolites 1 and 2 are not expected to cause clinically significant interactions with substrates of transporters such as P-glycoprotein, breast cancer resistance protein (BCRP) and organic anionic or cationic transporters.

5.3. Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated-dose toxicity, genotoxicity, carcinogenicity, juvenile toxicity, or toxicity to reproduction and development.

The repeated-dose toxicology studies demonstrated that administration of crisaborole by both the dermal and oral routes in mice, rats, and minipigs at plasma exposures up to 11 times that in humans did not result in significant toxicity relevant to its use in humans.

Crisaborole revealed no evidence of mutagenic or clastogenic potential based on the results of two *in vitro* genotoxicity tests (Ames assay and human lymphocyte chromosomal aberration assay) and one *in vivo* genotoxicity test (rat micronucleus assay).

In an oral carcinogenicity study in Sprague-Dawley rats, oral doses of 30, 100, or 300 mg/kg/day crisaborole were administered once daily. A crisaborole-related increased incidence of benign granular cell tumors in the uterus with cervix and vagina (combined) was noted in 300 mg/kg/day crisaborole-treated female rats (2 times the maximum recommended human dose (MRHD) on an area under the curve (AUC) comparison basis). The clinical relevance of this finding is unknown, however given the tumor type and benign status in a single species and single sex, the relevance to humans is considered to be low.

In a dermal carcinogenicity study in CD-1 mice, topical doses of 2%, 5%, or 7% crisaborole ointment were administered once daily. No crisaborole-related neoplastic findings were noted at topical doses up to 7% crisaborole ointment (1 times the MRHD on an AUC comparison basis).

Crisaborole was not found to be a reproductive toxicant nor a teratogen in reproductive toxicology studies at maternally non-toxic doses that examined effects on fertility, embryo-fetal development, and the F1 generation. Maternal toxicity in pregnant rats (associated with decreased fetal body weight and delayed skeletal ossification) but no crisaborole-related fetal malformations were noted after oral administration of crisaborole during organogenesis at doses up to 600 mg/kg/day (13 times the MRHD on an AUC comparison basis). Crisaborole did not

cause adverse effects to the fetus at oral doses up to the highest dose tested of 100 mg/kg/day in pregnant rabbits administered during the period of organogenesis (2 times the MRHD on an AUC comparison basis).

In a rat prenatal/postnatal development study, pregnant rats were treated with crisaborole at doses of 150, 300, or 600 mg/kg/day by oral gavage during gestation and lactation (from gestation day 7 through day 20 of lactation). Crisaborole did not have any adverse effects on fetal development at doses up to 300 mg/kg/day (3 times the MRHD on an AUC comparison basis). Maternal toxicity was produced at the high dose of 600 mg/kg/day in pregnant rats and was associated with findings of stillbirths, pup mortality, and reduced pup weights.

No effects on fertility were observed in male or female rats that were administered oral doses up to 600 mg/kg/day crisaborole (13 times the MRHD on an AUC comparison basis) prior to and during early pregnancy.

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6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Paraffin, white soft
Propylene glycol (E 1520)
Glycerol monostearate 40-55 (Type I)
Paraffin, hard
Sodium calcium edetate
Butylated Hydroxytoluene

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

After first opening the container: 1 year.

6.4. Special precautions for storage

Store below 30 ºC. Do not freeze.

Keep the tube tightly closed.

6.5. Nature and contents of container

Multi-layered laminate tube with a high density polyethylene tube head with a peel seal, and a white polypropylene cap closure.

Box, 6 tubes @ 2.5 g;
Box, 1 tube @ 30 g.

Not all tube sizes may be marketed.

6.6. Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER NAME AND ADDRESS

Manufactured by:
Pharmacia & Upjohn Company LLC
Kalamazoo, United States (USA)

Imported by:
PT. Pfizer Indonesia
Jakarta, Indonesia

8. MARKETING AUTHORISATION NUMBER
XXXXXXX

HARUS DENGAN RESEP DOKTER

9. DATE OF REVISION OF THE TEXT

03/2024

Nama Generik: Crisaborole
Nama Dagang: STAQUIS®
Tanggal Berlaku CDS: 26 Mei 2022
Menggantikan: Tidak Ada
Disetujui oleh BPOM:

Leaflet kemasan: Informasi untuk pengguna

STAQUIS® 20 mg/g salep
Crisaborole

Baca semua bagian leaflet ini dengan cermat sebelum mulai menggunakan obat ini karena berisi informasi penting bagi Anda.
- Simpan leaflet ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker, atau perawat Anda.
- Obat ini telah diresepkan hanya untuk Anda. Jangan memberikannya kepada orang lain. Obat ini dapat membahayakan mereka, sekalipun tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter atau perawat Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Lihat bagian 13.

Isi leaflet ini:

1. Nama obat

STAQUIS®

2. Bentuk sediaan

Salep.

3. Deskripsi obat

Salep berwarna putih hingga putih tulang.

4. Apa kandungan obat ini?

Zat aktifnya adalah crisaborole.

Satu gram salep mengandung 20 mg crisaborole.

Eksipien dengan efek yang diketahui:
Obat ini mengandung 90 mg propilen glikol dalam setiap gram salep.

Bahan yang lain adalah parafin, putih dan lembut; gliserol monostearat 40-55 (Tipe I); parafin, keras; natrium kalsium edetat; butil hidroksitoluen.

5. Kekuatan obat

2% (20 mg/g).

6. Apa kegunaan obat ini?

STAQUIS® digunakan pada kulit untuk mengendalikan gejala dermatitis atopik ringan hingga sedang pada orang dewasa dan anak-anak dan remaja mulai usia 2 tahun. Dermatitis atopik, juga disebut eksim atopik, menyebabkan peradangan, kemerahan, gatal-gatal, kulit kering, dan penebalan kulit pada orang-orang yang rentan terhadap alergi.

Bagaimana cara kerja STAQUIS®

Crisaborole, zat aktif dalam STAQUIS®, bekerja dengan mengurangi peradangan dan beberapa efek dari sistem kekebalan tubuh (pertahanan tubuh).

7. Berapa banyak dan seberapa sering Anda seharusnya menggunakan obat ini? Apa yang harus dilakukan jika ada dosis yang terlewat?

Gunakan obat ini tepat sesuai anjuran dokter atau apoteker Anda. Tanyakan kepada dokter atau apoteker jika Anda merasa tidak yakin.

Penggunaan pada orang dewasa
- Oleskan selapis salep dua kali sehari pada area kulit yang sakit.
- Obat ini dapat digunakan pada semua area kulit.
- Obat ini hanya boleh digunakan pada kulit.
- Cuci tangan Anda setelah mengoleskan obat ini, kecuali jika tangan Andalah yang diobati. Jika orang lain yang mengoleskan obat ini, mereka harus mencuci tangan setelah mengoleskan.

Penggunaan pada anak-anak dan remaja
Untuk anak-anak berusia 2 tahun ke atas dan remaja, petunjuk penggunaannya sama dengan orang dewasa.

Jika Anda lupa menggunakan STAQUIS®
Jika Anda lupa mengoleskan salep pada waktu yang dijadwalkan, lakukan segera setelah Anda ingat dan kemudian lanjutkan jadwal pemberian salep yang normal.

Jika Anda memiliki pertanyaan lebih lanjut terkait penggunaan obat ini, tanyakan kepada dokter, apoteker, atau perawat Anda.

8. Kapan seharusnya Anda tidak menggunakan obat ini?

Jangan menggunakan STAQUIS® jika:

- jika Anda alergi terhadap crisaborole atau terhadap bahan-bahan lainnya dalam obat (dicantumkan di bagian 6).

9. Apa yang harus dipertimbangkan saat menggunakan obat ini?

Konsultasikan dengan dokter, apoteker, atau perawat Anda sebelum menggunakan STAQUIS®.

Peringatan dan tindakan pencegahan
Konsultasikan dengan dokter atau apoteker Anda sebelum menggunakan STAQUIS®.

STAQUIS® tidak boleh digunakan pada mata, mulut, atau vagina; oleh karena itu berhati-hatilah agar salep ini tidak sampai mengenai area tersebut. Jika salep tidak sengaja mengenai mata atau membran mukosa, seka secara menyeluruh dan/atau bilas salep menggunakan air.

Segera hentikan penggunaan STAQUIS® dan kunjungi dokter jika Anda mengalami reaksi alergi. Gejalanya antara lain kaligata, gatal-gatal, pembengkakan, dan kemerahan yang berat.

10. Apa saja obat lain atau makanan yang harus dihindari selama menggunakan obat ini?

Beri tahu dokter atau apoteker Anda jika Anda sedang menggunakan, baru-baru ini menggunakan, atau mungkin menggunakan obat-obatan lain.

Beberapa jenis obat dapat memengaruhi kadar STAQUIS® dalam tubuh Anda. Anda harus memberi tahu dokter jika Anda sedang menggunakan obat-obatan termasuk yang menginduksi atau menghambat enzim sitokrom P450 (CYP).

Emolien, yang digunakan untuk melembapkan dan meredakan kulit kering, dapat digunakan pada bagian kulit lainnya sewaktu menggunakan STAQUIS®. Konsultasikan dengan dokter Anda tentang cara menggunakan emolien sewaktu menggunakan STAQUIS®.

11. Apakah obat ini aman untuk ibu hamil dan menyusui?

Kehamilan dan menyusui
Jika Anda sedang hamil atau menyusui, mengira Anda sedang hamil, atau berencana untuk hamil, mintalah saran dari dokter atau apoteker Anda sebelum menggunakan obat ini. Efek obat ini pada ibu hamil masih belum diketahui; oleh karena itu jangan menggunakan STAQUIS® selama kehamilan kecuali Anda telah berkonsultasi dengan dokter dan diperbolehkan untuk menggunakannya.

Tidak diketahui apakah STAQUIS® terbawa bersama ASI setelah dioleskan ke kulit. Efek obat ini pada bayi yang menyusui masih belum diketahui; oleh karena itu STAQUIS® tidak boleh digunakan jika Anda sedang menyusui atau berencana untuk menyusui.

12. Apakah pasien diizinkan mengemudi dan mengoperasikan mesin saat menggunakan obat ini?

STAQUIS® kemungkinan tidak menimbulkan efek terhadap kemampuan Anda untuk mengemudi dan mengoperasikan mesin.

13. Apa saja potensi efek yang tidak diinginkan dari penggunaan obat ini?

Seperti obat-obatan lainnya, obat ini dapat menimbulkan efek samping, sekalipun tidak semua orang mengalaminya.

Efek samping lainnya antara lain:

Umum (dapat dialami oleh 1 di antara 10 orang)
- Reaksi kulit di tempat mengoleskan obat ini seperti nyeri (panas atau sensasi tersengat), gatal-gatal, ruam, kemerahan, iritasi, dan kaligata.

Reaksi kulit yang paling umum adalah rasa nyeri (panas atau sensasi tersengat), biasanya dalam tingkat ringan hingga sedang dan umumnya akan mereda setelah beberapa kali aplikasi.

Melaporkan efek samping
Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter, apoteker, atau perawat Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Dengan melaporkan efek samping, Anda bisa membantu memberikan informasi lebih banyak mengenai keamanan obat ini.

14. Apa yang harus dilakukan jika Anda menggunakan lebih dari dosis yang dianjurkan?

Jika Anda terlalu banyak mengoleskan STAQUIS®, kelebihannya harus diseka.

15. Bagaimana cara menyimpan obat ini?

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Jangan menggunakan obat ini melebihi tanggal kedaluwarsa yang tertera pada tube dan dus setelah tanda EXP. Tanggal kedaluwarsa mengacu pada tanggal terakhir di bulan tersebut.

Simpan di bawah suhu 30 ºC. Jangan dibekukan.

16. Berapa lama masa simpan obat sejak wadah pertama kali dibuka?

Setelah dibuka, gunakan isi tube dalam waktu 1 tahun.

Jaga agar tube selalu tertutup rapat.

Jangan buang obat melalui saluran pembuangan air atau bersama sampah rumah tangga. Tanyakan kepada apoteker mengenai cara membuang obat yang sudah tidak digunakan lagi. Langkah-langkah ini akan membantu melindungi lingkungan.

17. Nomor izin edar

Dus, 6 tube @ 2.5 g;
Dus, 1 tube @ 30 g.

XXXXXXX

18. Nama dan alamat pemohon dan/atau pemilik obat sesuai dengan ketentuan yang berlaku

Diproduksi oleh:
Pharmacia & Upjohn Company LLC
Kalamazoo, United States (USA)

Nama Generik: Crisaborole
Nama Dagang: STAQUIS®
Tanggal Berlaku CDS: 26 Mei 2022
Menggantikan: Tidak Ada
Disetujui oleh BPOM:

Diimpor oleh:
PT. Pfizer Indonesia
Jakarta, Indonesia

19. Tanggal revisi
11/2023

20. Peringatan khusus
HARUS DENGAN RESEP DOKTER