


NAZWA PROJEKTU / PROJECT IMMUFEN KREM ULOTKA IU		KLIENT / CLIENT DELIA		KOLORY / COLOURS  BLACK	DODATKI / ADDITIONS
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UWAGI / NOTES ulotka: 140 x 210 mm szer. x wys. x głęb. / width x height x depth	SUROWCE / RAW MATERIAL ulotka:				
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Pažljivo pročitajte priloženo uputstvo za upotrebu medicinskog sredstva Immufen Onco Hand-Foot Syndrome Cream jer sadrži važne informacije za pacijente o njegovoj upotrebi. Uputstvo sačuvajte za slučaj da treba ponovo da ga pročitate.

Tokom hemioterapije i radioterapije sledite uputstva lekara.

Uputstvo za upotrebu

Immufen Onco Hand-Foot Syndrome Cream Medicinsko sredstvo 100 mL

1. Šta je Immufen Onco Hand-Foot Syndrome Cream?

Immufen Onco Hand-Foot Syndrome Cream je medicinsko sredstvo sa sastojcima koji na koži stvaraju zaštitni film sa hidrirajućim i lubrikantnim efektom. Nastali film ublažava neželjena dejstva koja se javljaju tokom primene nekih hemioterapeutika i bioloških lekova, kao što je Sindrom šaka-stopalo (Hand-Foot syndrome, palmo-plantarna eritrodisestezija).

2. Za šta se koristi Immufen Onco Hand-Foot Syndrome Cream?

Sindrom šaka-stopalo je neželjena reakcija na hemioterapiju, karakteristična za mnoge hemioterapeutike i biološke lekove koji su trenutno u upotrebi. Počinje kao osećaj trnjenja, pečenja i ukočenosti na površini šaka i stopala. Kasnije se javljaju crvenilo i produženi bol. Drugi simptomi ovog sindroma su: keratinizacija, ljuštenje, izbočenja i pucanje kože. Takođe se mogu pojaviti i plikovi i čirevi na koži. Ovi simptomi ne samo da utiču na kvalitet života pacijenta, već mogu, ako su veoma ozbiljnog karaktera, da uzrokuju smanjenje terapijske doze ili čak privremeni prekid terapije. Zato je veoma važna odgovarajuća zaštita šaka i stopala u cilju sprečavanja i ublažavanja simptoma ovog sindroma. Preporučuje se i izbegavanje primene supstanci koje jako iritiraju kožu, kao što su parfemi i snažna sredstva za pranje, zatim vruće kupke, nošenje preuskih cipela i prekomerno izlaganje suncu. Takođe se preporučuje i redovna upotreba krema koje vlaže i omekšavaju kožu, a naročito onih koje sadrže ureu, da bi se sprečila keratinizacija kože.

Immufen Onco Hand-Foot Syndrome Cream sadrži 10 % uree, koja intenzivno vlaži i omekšava iritiranu kožu. Supstance Omega Plus kompleksa, Shea buter, proteini svile i SyriCalm™, koje se takođe nalaze u kremu, vlaže i podmazuju kožu čime obezbeđuju zaštitu kože od štetnih spoljnih faktora. Oni takođe stvaraju odgovarajuću sredinu za prirodni regenerativni proces. Pravilna hidratacija i lubrikacija kože ublažava simptome poput svraba, pečenja i osećaja zategnutosti kože.

3. Doziranje i način primene

Immufen Onco Hand-Foot Syndrome Cream treba koristiti prema uputstvu za upotrebu.

Kako primeniti:

Primenjivati samo na čistoj i neoštećenoj koži. Malu količinu krema nanosite na kožu šaka i stopala i nežno razmažite. Počnite sa primenom krema nekoliko dana pre prve hemioterapije ili primene biološkog leka. Nastavite sa redovnom primenom, prema potrebi više puta dnevno u toku dana, a naročito nakon pranja i sušenja šaka i stopala ili nakon korišćenja iritirajućih agenasa. Nakon prekida osnovne terapije, primenu krema treba nastaviti još najmanje dve nedelje.

U slučaju bilo kakvih pitanja, obratite se Vašem lekaru.

Ovo medicinsko sredstvo je namenjeno za primenu kod odraslih i dece starije od 3 godine.

4. Kontraindikacije

Preosetljivost (alergija) na sastojke proizvoda.

Ne primenjivati na otvorene rane ili na rane sa prisutnim oštećenjem dermisa. Izbegavati kontakt sa očima.

5. Uslovi čuvanja

Čuvati u originalnom pakovanju, na temperaturi do 25°C.

Čuvati van vidokruga i domašaja dece.

6. Sastav

Aktivne supstance: urea, SyriCalm™ CLR (Phragmites kharka i Poria cocos ekstrakti), Shea buter, Omega Plus kompleks (suncokretovo ulje, kukuruzno ulje, susamovo ulje, ulje semenki makadamije, maslinovo ulje), hidrolizovani proteini svile, glicin sojino ulje.

Pomoćne supstance: voda, glicerol, vazelin, cetearilalkohol, glicerolstearat, fenoksietanol, etilheksil glicerol, stearyl natrijum glutamat, natrijum poliakrilat, trietanolamin, mlečna kiselina, aroma belog čaja, dinatrijum EDTA, vosak, stabilizator (PEG-8, tokoferol, askorbil palmitat, askorbinska kiselina, limunska kiselina), imidazolidinil urea, kalijum-sorbat, natrijum-benzoat.

7. Opis pakovanja

Unutrašnje pakovanje medicinskog sredstva Immufen Onco Hand-Foot Syndrome Cream je plastična tuba u kojoj se nalazi 100 mL krema.

Spoljašnje pakovanje sadrži kutiju, tubu i uputstvo za upotrebu.



Proizvođač:

Gofarm Sp.z.o.o.Sp.k,
Gornikow 21/26 street, 30-819 Krakow, Poljska

Ovlašćeni predstavnik u Srbiji: Salveo d.o.o. Beograd

Tošin bunar 272, Beograd

Broj rešenja o registraciji: 515-02-01811-19-005 od 28.11.2019.

Nosilac upisa u Crnoj Gori: Salveo CG d.o.o. Podgorica

Milutina Kažića 19, Podgorica

Broj rešenja:



Simboli na pakovanju:



Proizvođač



Važi do



Broj serije



Pre primene pročitati uputstvo za upotrebu



Maksimalna temperatura čuvanja



Medicinsko sredstvo



Ne koristiti ako je pakovanje oštećeno.

Datum revizije uputstva: August 2019.

IMHFSC/IU/08/2019

Carefully read the instructions for use contained in the package, as it contains important information for the patient about the use of the product **Immufen - Onco Hand-Foot Syndrome Cream**, and then store it in case the need to re-read.

During chemo and radiotherapy act in accordance with doctor's instructions.

Instructions for use
Immufen - Onco Hand-Foot Syndrome Cream
Medical device
100 ml

1. What is Immufen - Onco Hand-Foot Syndrome Cream

Immufen - Onco Hand-Foot Syndrome Cream is a medical device in form of cream, rich in ingredients which form on skin moisturising-lubricating protective barrier. Created film, eases course of side effect, of some chemotherapeutics and biological medicines, like Hand-Foot Syndrome (palmar plantar erythrodysesthesia). The cream should be used as support for main oncological therapy (chemotherapy).

2. What is Immufen - Onco Hand-Foot Syndrome Cream used for ?

Hand-Foot Syndrome is a side effect of chemotherapy, characteristic for many currently used chemotherapeutics and biological medicines. It starts with tingling sensation, burning and stiffening on the hands and feet surface. Afterwards redness and proceeding pain appears. Other symptoms of that syndrome are: keratinization, desquamation, protrusion and fracture of the skin. Also blisters and ulcers can appear. These symptoms not only influence the life comfort of the patients but also when are very serious can cause lowering of therapeutic dose or even temporary treatment termination. Therefore very important is proper protection of hand and feet to prevent and ease of occurring symptoms of syndrome. It is recommended to avoid strong skin irritating substances like perfumes, forceful washing compounds, hot baths, wearing too tight shoes and excessive sun exposure. It is also recommended to regular use of moisturizing and softening creams, which prevent keratinization of the skin, particular those containing urea.

Immufen - Onco Hand-Foot Syndrome Cream contains 10% of urea, which intensely moisturises and softens irritated skin. Additionally contained in the product substances like Omega Plus Complex, Shea butter, silk proteins or SyriCalm, lubricate and moisturise skin, so that ensuring protective barrier from harmful external factors. They also create proper environment for natural regenerating processes. Proper moisturizing and lubrication of the skin, decreasing symptoms of itching, burning and tightness.

3. Dosage and how to use

Immufen - Onco Hand-Foot Syndrome Cream should be used according to instructions for use.

How to use:

Use on clean and undamaged skin. Small amount of cream apply to the skin of your hands and feet. Gently spread. Start the application few days before first chemotherapy or biological medicines intake. Then use regularly, few times a day according to needs, especially after washing and drying of hands and feet and after using irritating agents. After termination of basic therapy the cream should be used for at least 2 weeks.

In case of any questions contact your physician.

The device is intended for adults and children over 3 years of age.

4. Contraindications

Hypersensitivity (allergy) to product ingredients.
Do not use on open not-healed wounds and for the injury with infraction of dermis.
Avoid contact with eyes.

5. Storage conditions

Store in original container in room temperature below 25°C.
Keep out of reach and sight of children.

6. Composition

Main ingredients: urea, SyriCalm™ CLR (extracts from Phragmites kharka and Poria cocos), shea butter, oil complex Omega Plus (Helianthus annuus seed oil, Zea mays oil, Sesamum indicum seed oil, Macadamia integrifolia seed oil, Olea europaea fruit oil), hydrolyzed silk, glycine soja oil.

Additive ingredients: aqua, glycerin, petrolatum, cetearyl alcohol, glycerol stearate, phenoxyethanol, ethylhexylglycerin, stearyl sodium glutamate, sodium polyacrylate, aroma of white tea, disodium EDTA, beeswax, triethyl citrate, stabilizer (PEG-8, tocopherol, ascorbyl palmitate, ascorbic acid, citric acid), imidazolidinyl urea, potassium sorbate, sodium benzoate.

7. Packaging description

Immufen - Onco Hand-Foot Syndrome Cream is packed in plastic tube with 100 ml of device.

The unit packaging contains: box, tube and instructions for use.



Manufacturer:

Gofarm Sp. z o.o. Sp.k.
Górników 21/26 street
30-819 Kraków
www.gofarm.pl

Manufactured for:

Sanagen Pharm Ltd, Borongajska cesta 83 H, Zagreb, Croatia
www.immufen.com



Symbols presented on the packaging



Manufacturer



Expiration date



Batch number



See instructions for use



Maximal storage temperature



Medical device



Do not use if the package is damaged

Date of instructions for use actualization: August 2019
IMHFSC/IU/08/2019