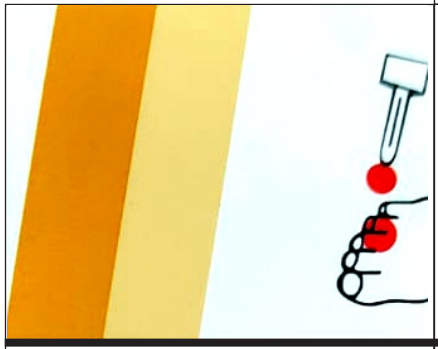


10ml

COLLOMAK SOLUTION

For External Use Only

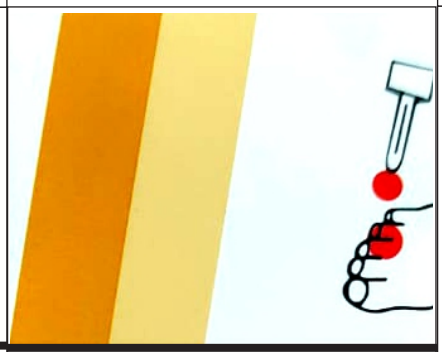
Manufactured By:
OCTOBER PHARMA S.A.E.
6 October City, Industrial Zone, Plot 190, Egypt.
E-mail: info@octoberpharma.com

October Pharma
Made in Egypt

Marketed by:
Smart way Pharma
61, Thomas Animashaun Street, Aguda, Lagos.

NAFDAC REG. NO.: B4-6140

Batch No.: A04400922
Mfg. Date: 9/22
Exp. Date: 9/26



Composition (Per 10 g)

Salicylic acid	2.0g
Lactic acid	0.5g
Polidocanol	0.2g

Indication and dosage:
See enclosed insert

10ml

COLLOMAK SOLUTION

Caution & Warnings:
For external use only.

Store below 30^{0}C.

Keep out of the reach of Children.

SUMMARYOF PRODUCTCHARACTERISTICS

1 NAMEOFTHEMEDICINALPRODUCT

COLLOMAK

2 QUALITATIVEANDQUANTITATIVECOMPOSITIONS

alicylicacid 2.0% w/w
Lactic acid0.5%w/w
Polidocanol 0.2%w/w

3 PHARMACEUTICALFORM

Solutionfortopicaladministration.

4 CLINICALPARTICULARS

4.1 Therapeutic indications

Collomakisindicatedforthetreatmentof warts.

4.2 Posologyandmethodofadministration

Adults, the elderly and children aged 2 years and over.Applydailytotheaffectedareas only.
Children:

Children under the age of 12 years should be treated under supervision.Treatmentofinfantsunderthe ageof 2yearsisnotrecommended.

Collomak should be applied to the wart once daily preferably at bedtime.Procedurefor application:

1. The wart should be soaked in warm water for 5 minutes and dried thoroughlywithacleantowel.
2. The surface of the wart should be rubbed with a nail file, pumice stone, emeryboardor coarse washcloth,with caretaken notto causebleeding.
3. A thin layer of Collomak should be applied directly to the wart. Care should betakentoavoid the healthysurroundingskin.
4. The solution should be allowed to dry thoroughly. The wart should be coveredwith a plaster (dressing) if it is large or if it is on the foot to help penetration ofingredients.

It is recommended that treatment continues until whichever of the following occursfirst:

- Wartshavebeentreatedfor12weeks
- The wart is completely cleared and the normal ridgelines of the skin have beenrestored.

For warts, clinically visible improvement should occur in 1-2 weeks, but themaximumeffectmaybe expected after 4-8weeks.

If warts persist beyond 12 weeks of treatment, the patient should be advised toconsulttheirpharmacist ordoctor.

Consider alternative treatments if warts cover a large area of the body (more than $5cm^2$)(see Warnings and Precautions).

Patients should be advised to consult a pharmacist or doctor if skin irritationdevelops.

Due to the flammable nature of Collomak, patients should avoid smoking or being nearanopenflame duringapplication and immediatelyafter use.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section6.1.

Donotuseonopen wounds,irritatedor reddened skin,oranyareathatisinfected.

Collomak should not be used on the face, anogenital regions, moles, birthmarks,mucous membranes, warts with hair growing from them, red edges or an unusualcolour.Avoid applyingto normal skin.

4.4 Specialwarningsandprecautionsforuse

Collomakcontainscolophonywhichmaycauseallergiccontactdermatitis.

This medicine contains 10%v/v ethanol in each application. It may causeburningsensation ondamaged skin.

Collomak may cause eye irritation. Avoid contact with eyes and other mucousmembranes. In case of accidental contact with the eyes or other mucousmembranes,flushwithwaterfor15minutes.

Avoid exposure to healthy skin (see Adverse Reactions). Collomakmay causeskin irritation. If undue skin irritation develops treatment should bediscontinued.

Consider alternative treatments if warts cover a large area of the body (morethan5cm^2)duetothepotentialriskofsalicylatetoxicity.

Collomakisnot recommendedin patientswithdiabetes, circulatoryproblems orperipheralneuropathyexceptunderthesupervisionofadoctor.

Oral salicylates taken during or immediately after a viral illness have beenassociated with Reye's syndrome and hence there is a theoretical risk withtopicalsalicylates.

Therefore, use is not advised in children or teenagers during or immediatelyafterchickenpox,influenza,orotherviralinfections.

Ithasbeenreportedthatsalicylatesareexcretedviabreastmilk(see *PregnancyandLactation*).

Patients should be advised not to inhale the

vapour.Keepoutofthesightandreachofchildren.

4.5 Interactionwithothermedicinalproductsandotherformsofinteraction

Topical collomak may increase the absorption of other topically applied medicines.Therefore, concomitant use of collomak and other topical medicines on the treatedarea should be avoided. As systemic exposure of topically applied Collomak is low,interactionwithsystemicallyadministered medicinesisnot anticipated.

4.6 Fertility,Pregnancyandlactation

Pregnancy

The safety of Collomak during human pregnancy has not been established. Studies inanimals given salicylic acid orally demonstrated embryo toxicity at high doses (seeNon-ClinicalInformation).

Collomakisnotrecommendedduringpregnancy.

Lactation

Salicylates are excreted in human milk. Collomak is not recommended duringlactation.

If used or administered during lactation, care should be taken to avoid contact withthebreastareainorderto avoid accidental ingestion bythe infant.

4.7 Effectsonabilitytodriveandusemachines

None

4.8 Undesirableeffects

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class andbyfrequency.Frequenciesaredefinedas:verycommon(≥1/10),common(≥1/100and<1/10),uncommon(≥1/1,000and<1/100),rare(≥1/10,000and<1/1,000)andveryrare (<1/10,000), includingisolatedreports.

Clinical Trial

DataImmunesystemdisor

ders

Common: Rash

Skinandsubcutaneoustissuedisorders

Very common: Application site reaction, pruritus, burning sensation,erythema,scaling, dryness

Common: Skinhypertrophy

Post Marketing

DataImmunesystemdisor

ders

Rare: Applicationsitehypersensitivityincludinginflammation

Skinandsubcutaneoustissuedisorders

Rare: Applicationsitepainandirritation

Applicationsitediscoloration/skindiscoloration

Exposure to healthy skin can lead to application siteblistering and skin exfoliation (*see Warnings andPrecautions*).

Allergicdermatitis

Reportingof suspectedadversereactions

Reporting suspected adverse reactions after authorisation of the medicinal product isimportant.Itallowscontinuedmonitoringofthebenefit/riskbalanceofthemedicinalproduct. Healthcare professionals are asked to report any suspected adverse reactionsviathe YellowCard Schemeat:www.mhra.gov.uk/yellowcard.

4.9 Overdose

SymptomsandSigns

Intheeventofaccidentaloralingestionsymptomsofsalicylatetoxicitymayoccur.

The risk of developing symptoms of salicylate poisoning or salicylism is increased ifCollomak is used excessively or if it is used for prolonged periods of time. Therefore,durationofuse andrecommendedfrequencycomplianceis veryimportant.

Treatment

Managementshouldbeasclinicallyindicated.

5 PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamicproperties

ATCCode

Pharmacotherapeutic group: Wart and anti-corn

preparations.ATCcode:D11AF

Lactic acid affects the keratinisation process, reducing the hyperkeratosis which ischaracteristic of warts. At high concentrations it can cause epidermolysis, leading tothe destruction of the keratotic tissue of the wart and of the causative virus. It also hasantisepticproperties.

Flexible collodion provides a viscous vehicle that allows accurate application of theactive ingredients to the wart. It also forms a film that helps to hydrate and promotethedestruction ofwarttissue.

Salicylic acid is keratolytic, producing desquamation by solubilising the intercellularcementinthestratumcorneumresultinginthesheddingofskin scales.

5.2 Pharmacokineticproperties

Absorption

Salicylic acid is absorbed through the skin; where detectable, maximum plasma levelsare found 6 to 12 hours after application. Systemic absorption of salicylic acid hasbeen reported to range from 9% to 25% after topical application of other salicylicacid-containing preparations. The extent of absorption is variable depending on theduration of contact and the vehicle. Despite percutaneous absorption, the systemicexposure is low given the low dose topically administered to small, localised areas ofhyperkeratotictissue.

Human abdominal skin in a flow-through diffusion system was used to assess the invitro percutaneous absorption of lactic acid. At a pH of 3, the amount of radioactivitydetected in the receptor fluid, stratum corneum, epidermis, and dermis was 3.6, 6.3,6.6,and 13.9%, respectively.

Distribution

Following percutaneous absorption, salicylic acid is distributed in the extracellularspace;approximatelyhalfofwhich isprotein bound toalbumin.

Metabolism

Salicylates are metabolised in the liver by microsomal enzymes to salicyluric acid andphenolic glucuronides of salicylic acid. That which is not metabolised is excreted intheurine asunchanged salicylic acid.

Elimination

Within 24 hours of salicylic acid being absorbed and distributed in the intercellularspace,approximately95%ofthe absorbeddosecanberecovered intheurine.

5.3 Preclinicalsafetydata

Notapplicable.

6 PHARMACEUTICALPARTICULARS

6.1 List ofexcipients

6.2 Dibutyl phthalate, ethyl cellulose 100 CPS, acetone.

6.3 Incompatibilities

None.

6.4 Shelf life

a) Forthe productas packagedforsale

3years

b) Afterfirstopeningthecontainer

Complywith expirydate

6.5 Specialprecautionsforstorage

Donot store above 30°C.Keep awayfromnaked flame.

6.6 Natureandcontentsofcontainer

Amberscrewcappedapplicatorbottlecontaining15ml.

6.7 Specialprecautionsfordisposal

TherearenospecialinstructionsforuseorhandlingofCollomak.

7 MARKETINGAUTHORISATION HOLDER

Smart way Pharma
Ltd
61, Thomas
Animashaun Street,
Aguda, Lagos.

8 MARKETINGAUTHORISATION NUMBER(S)

9 DATEOFFIRSTAUTHORISATION/RENEWALOFTHEAUTHORISATION

10 DATEOFREVISIONOFTHETEXT