

GYNOX-SOFT - boric acid emulsion
SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

GYNOX-SOFT NEUTRAL, SCENTED AND TEEN, Foamy emulsion for Intimate hygiene

GYNOX-SOFT is a foaming emulsion with Boric acid that is a antiseptic agent to control the microbial load present in the intimate area.

GYNOX SOFT NEUTRAL, SCENTED OR TEEN, bubble bath is an antibacterial action, cleaning, fungicidal, and antibacterial that can be used by the whole family, including new borns.

This product must be out of reach of children

GYNOX-SOFT is intimate hygiene foaming emulsion and body for men, women and teenagers of antibacterial action. Is pH balanced, is in daily use before, during and after the menstrual cycle, deep asepsis of hands skin complaints and scalp.

Suspend its use if you observed any desfavorable reaction. This product may be irritate your skin if you do not follow the recommended instructions. Contact with eyes may produce irritation and burning sensation; if this occurs flush your eyes immediately with fresh water.

This product is for topical application. Add in the application area amount of product, rub gently to obtain foam and rinse.

This product is an emulsion, made with ingredients that provide moisturization, and protection in the intimate area. Is non toxic and has no known contraindications.

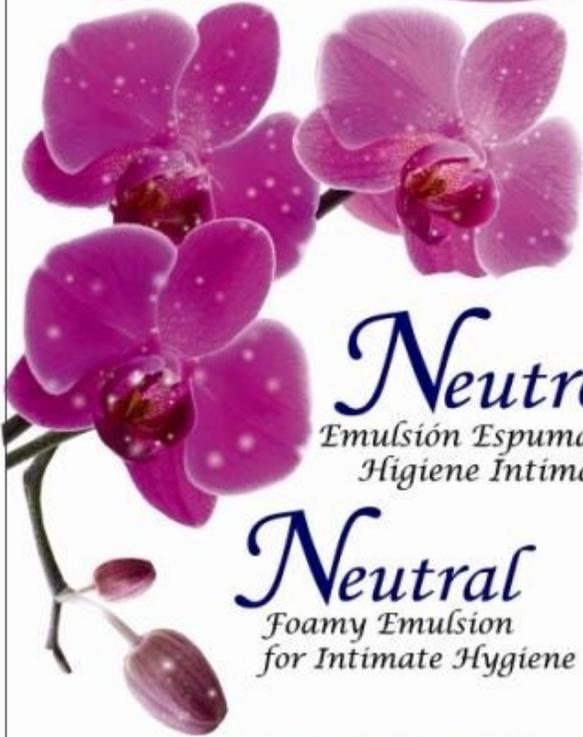
IMAGE OF THE LABEL

For Export

SPAI SONS

pH Intimo
Uso Externo

Gynox Soft



Neutro
Emulsión Espumante
Higiene Íntima

Neutral
Foamy Emulsion
for Intimate Hygiene

Net Content 1 qt (1000ml)

GYNOX SOFT - Neutro

Emulsión espumante, higiene íntima.

Baño de espuma suavemente perfumado, para la higiene íntima y corporal. El empleo diario desodoriza, limpia muy bien.

GYNOX SOFT, no es tóxico y por su excelente tolerancia puede ser empleado por mucho tiempo.

ADVERTENCIAS: si observa alguna reacción desfavorable suspenda su empleo. Este producto puede ser irritante si no sigue las instrucciones para el uso. Manténgase fuera del alcance de los niños. El contacto con los ojos puede producir ardor pasajero, si este es el caso lavar con agua pura.

USO EXTERNO: aplicar frotando con la yema de los dedos y retirar la espuma con abundante agua.

INGREDIENTES: Agua, Laureth Sulfato Sódico, Decil Glucosido, Lauroil Lactilato sódico, Cocamida DEA, Extracto de Flores de Calendula Officinalis, Propilén Glicol, Glicol Distearato, Coco-Glucosido, Gliceril Oleato, Ácido Bórico, Extracto de flores de Chamomilla Recutita, PEG-120 Metil Glucosa Dioleato, Triclosan, Extracto de Urtica Dioica, Metil Parabeno, Fragancia, Cloruro Sódico, Ácido Cítrico, Propil Parabeno, +/- CI 16035.

GYNOX SOFT - Neutral

Foamy Emulsion for intimate hygiene

Foamy cleanser with a delicate soft scent used for intimate and body hygiene. Daily use will provide a clean deodorizing scent and a deep sense of cleanliness.

GYNOX SOFT is not toxic and because of its extraordinary tolerance it may be used for prolonged periods of time.

WARNINGS: Suspend its use if you observe any unfavorable reaction. This product may irritate your skin if you do not follow the recommended instructions. Keep out of reach of children. Contact with eyes may produce irritation and burning sensation; if this occurs flush your eyes immediately with fresh water.

RECOMMENDED EXTERNAL USE: Apply rubbing with fingertips and remove the foam using abundant water.

INGREDIENTS: Water, Sodium Laureth Sulfate, Decyl glucoside, sodium lauroyl lactylate, Cocamide DEA, Calendula Officinalis Flower Extract, Propylene Glycol, Glycol Distearate, Coco-Glucoside, Glycerol Oleate, Boric Acid, Chamomille Recutita flower Extract, PEG-120 Methyl Glucose Dioleate, Triclosan, Urtica Dioica Extract, Methylparaben, Fragrance, Sodium Chloride, Citric Acid, Propylparaben, +/- CI 16035.

Conservese en envase original herméticamente sellado.



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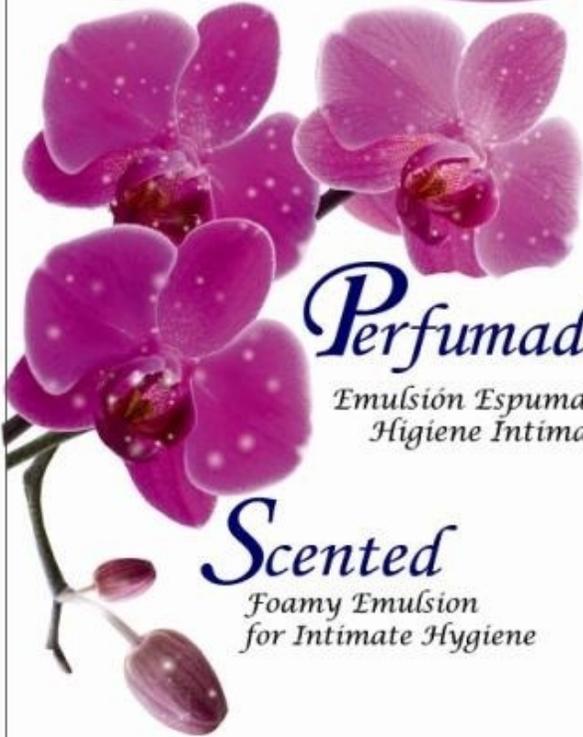
Manufactured by SPAI-SONS Pharmaceutical International Cosmetics.
Notif. Sanit. NSOC40305-10CO for American SPAI-SONS USA Corp. MIAMI, FL (305)2066008
Distribuido por: All-Time Spai-sons Ecuatoriana/ Tulcan- Ecuador
Made in Bogotá Colombia /Phone: 4279090
www.spai-sons.com / ventas@spai-sons.com
Lot# No.

For Export

SPAI & SONS

*pH Intimo
Uso Externo*

Gynox Soft



Perfumado

*Emulsión Espumante
Higiene Intima*

Scented

*Foamy Emulsion
for Intimate Hygiene*

Net Content 1 qt (1000ml)

GYNOX SOFT - Perfumado **Emulsión espumante, higiene íntima.**

Baño de espuma suavemente perfumado, para la higiene íntima y corporal . El empleo diario desodoriza, limpia muy bien.

GYNOX SOFT, no es tóxico y por su excelente tolerancia puede ser empleado por mucho tiempo .

ADVERTENCIAS: si observa alguna reacción desfavorable suspenda su empleo. Este producto puede ser irritante si no sigue las instrucciones para el uso. Manténgase fuera del alcance de los niños. El contacto con los ojos puede producir ardor pasajero, si este es el caso lavar con agua pura.

USO EXTERNO: aplicar frotando con la yema de los dedos y retirar la espuma con abundante agua.

INGREDIENTES: Agua, Laureth Sulfato Sodico, Decil Glucosido,Lauroil Lactilato sodico,Cocamida DEA, Extracto de Flores de Calendula Officinalis, Propilen Glicol, Glicol Distearato, Coco-Glucosido, Gliceril Oleato,Acido Borico, Extracto de flores de Chamomilla Recutita, PEG-120 Metil Glucosa Dioleato, Triclosan, Extracto de Urtica Dioica, Metil Parabeno, Fragancia, Cloruro Sodico, Acido Citrico, Propil Parabeno,+/- CI 16035.

GYNOX SOFT - Scented **Foamy Emulsion for intimate hygiene**

Foamy cleanser with a delicate soft scent used for intimate and body hygiene. Daily use will provide a clean deodorizing scent and a deep sense of cleanliness.

GYNOX SOFT is not toxic and because of its extraordinary tolerance it may be used for prolonged periods of time.

WARNINGS: Suspend its use if you observe any unfavorable reaction. This product may irritate your skin if you do not follow the recommended instructions. Keep out of reach of children. Contact with eyes may produce irritation and burning sensation; if this occurs flush your eyes immediately with fresh water.

RECOMMENDED EXTERNAL USE: Apply rubbing with fingertips and remove the foam using abundant water.

INGREDIENTS: Water, Sodium Laureth Sulfate, Decyl glucoside, sodium lauroyl lactylate,Cocamide DEA, Calendula Officinalis Flower Extract, Propylene Glycol, Glycol Distearate, Coco-Glucoside,Glyceryl Oleate, Boric Acid, Chamomille Recutita flower Extract, PEG-120 Methyl Glucose Dioleate, Triclosan, Urtica Dioica Extract, Methylparaben, Fragrance, Sodium Chloride, Citric Acid, Propylparaben,+/- CI 16035.

Conservese en envase original herméticamente sellado.



Manufactured by SPAI-SONS Pharmaceutical International Cosmetics.

Notif. Sanit. NSOC40395-10CO for American

SPAI-SONS USA Corp. MIAMIFI (305)2066098

Distribuido por: All-Time Spai-sons Ecuatoriana/ Tulcan- Ecuador

Made in Bogotá Colombia /Phone: 4279090

www.spai-sons.com / ventas@spai-sons.com

Lote No.

pH Intimo
Uso Externo

Gynox Soft Teen

Productos Naturales de Alta Tecnología

Higiene Intima
para Jovencitas y Niñas

Intimate and personal Hygiene
for teenagers and little Girls

For Export
Net Content 8,6 Fl Oz (260ml)

SPAI SONS

GYNOX SOFT TEEN
Emulsión Espumante
Higiene Intima para jovencitas y Niñas

Baño de espuma suavemente perfumado, para la higiene íntima y corporal. El empleo diario desodoriza, limpia muy bien.

GYNOX SOFT, no es tóxico y por su excelente tolerancia puede ser empleado por mucho tiempo.

ADVERTENCIAS: si observa alguna reacción desfavorable suspenda su empleo. Este producto puede ser irritante si no sigue las instrucciones para el uso. Manténgase fuera del alcance de los niños. El contacto con los ojos puede producir ardor pasajero, si este es el caso lavar con agua pura.

USO EXTERNO: aplicar frotando con la yema de los dedos y retirar la espuma con abundante agua.

INGREDIENTES: Agua, Laureth Sulfato Sodico, Decil Glucosido, Lauroil Lactilato sodico, Cocamida DEA, Extracto de Flores de Calendula Officinalis, Propilen Glicol, Glicol Distearato, Coco-Glucosido, Gliceril Oleato, Acido Borico, Extracto de flores de Chamomilla Recutita, PEG-120 Metil Glucosa Dioleato, Triclosan, Extracto de Urtica Dioica, Metil Parabeno, Fragancia, Cloruro Sodico, Acido Citrico, Propil Parabeno, +/- CI 16035.

GYNOX SOFT TEEN - Foamy Emulsion for intimate hygiene for teenagers and little girls

Foamy cleanser with a delicate soft scent used for intimate and body hygiene. Daily use will provide a clean deodorizing scent and a deep sense of cleanliness.

GYNOX SOFT is not toxic and because of its extraordinary tolerance it may be used for prolonged periods of time.

WARNINGS: Suspend its use if you observe any unfavorable reaction. This product may irritate your skin if you do not follow the recommended instructions. Keep out of reach of children. Contact with eyes may produce irritation and burning sensation; if this occurs flush your eyes immediately with fresh water.

RECOMMENDED EXTERNAL USE: Apply rubbing with fingertips and remove the foam using abundant water.

INGREDIENTS: Water, Sodium Laureth Sulfate, Decyl glucoside, sodium lauroyl lactylate, Cocamide DEA, Calendula Officinalis Flower Extract, Propylene Glycol, Glycol Distearate, Coco-Glucoside, Glycerol Oleate, Boric Acid, Chamomille Recutita flower Extract, PEG-120 Methyl Glucose Dioleate, Triclosan, Urtica Dioica Extract, Methylparaben, Fragrance, Sodium Chloride, Citric Acid, Propylparaben, +/- CI 16035.

Conservarse en envase original herméticamente sellado.

Manufactured by SPAI-SONS Pharmaceutical International Cosmetics.

Notif. Sanit. NSOC40305-10CO for American SPAI-SONS USA Corp. MIAMI, FL (305)2066008

Distribuido por: All-Time Spai-sons Ecuatoriana/ Tulcan- Ecuador

Made in Bogotá Colombia /Phone: 4279090

www.spai-sons.com / ventas@spai-sons.com

Lote No.



GYNOX-SOFT

boric acid emulsion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:66854-003 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| BORIC ACID (UNII: R57ZHV85D4) (BORIC ACID - UNII:R57ZHV85D4) | BORIC ACID | 7 mg in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0K00R) | |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0) | |
| DECYL GLUCOSIDE (UNII: Z17H97EA6Y) | |
| SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO) | |
| COCO DIETHANOLAMIDE (UNII: 92005F972D) | |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |

| | |
|--|--|
| GLYCOL DISTEARATE (UNII: 13W7MDN21W) | |
| COCO GLUCOSIDE (UNII: ICS790225B) | |
| GLYCERYL OLEATE (UNII: 4PC054V79P) | |
| CHAMOMILE (UNII: FGL3685T2X) | |
| PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |

Product Characteristics

| | | | |
|-----------------|-----------------------------|---------------------|--|
| Color | white (BEIGE) , pink (PINK) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:66854-003-01 | 210 mL in 1 BOTTLE | | |
| 2 | NDC:66854-003-02 | 250 mL in 1 BOTTLE | | |
| 3 | NDC:66854-003-03 | 260 mL in 1 BOTTLE | | |
| 4 | NDC:66854-003-04 | 270 mL in 1 BOTTLE | | |
| 5 | NDC:66854-003-05 | 400 mL in 1 BOTTLE | | |
| 6 | NDC:66854-003-06 | 515 mL in 1 BOTTLE | | |
| 7 | NDC:66854-003-07 | 1000 mL in 1 BOTTLE | | |
| 8 | NDC:66854-003-09 | 30 in 1 BOX | | |
| 8 | NDC:66854-003-08 | 12 mL in 1 BAG | | |
| 9 | NDC:66854-003-10 | 500 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| unapproved drug other | | 06/30/2012 | |

Labeler - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

Registrant - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|------------------------------------|
| SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS | | 880172184 | analysis, label, manufacture, pack |

Revised: 6/2012

SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS