CHILDRENS TUKOL ACETAMINOPHEN FEVER REDUCER PAIN REDUCERacetaminophen liquid Genomma Lab USA, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Children's Tukol® Fever Pain 525

Drug Facts
Active ingredient
(in each 5 mL = 1 teaspoonful)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

temporarily

- reduces fever
- relieves minor aches and pains due to:
- the common cold
- flu
- headache
- sore throat
- toothache

Warnings

Liver warning: This product cantains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 24 hours which is the maxium daily amount
- with other drugs containing acetaminophen

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: if sore throat is severe, persists more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomitting, consult a doctor promptly.

Do not use

• with any other drug containing acetaminophen (prescription or non prescription). If you are not sure whether a drug containd acetaminophen, ask a doctor or pharmacist

Ask a doctor before use if the child has

liver disease

Ask a doctor or pharmacist before use if the child is

taking the blood thinning drug warfarin.

When using this product

do not exceed recommended dose (see overdose warning)

Stop use and ask a doctor if

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more tha 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition

Keep out of reach of children.

Keep out of reach of children.

Overdose warning:

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions *

- product is not labeled with directions or complete warning for adult use
- Shake well before using
- 1mL = milliliter; tsp = teaspoonful
- find the right dose on chart below. If posssible, use weight to dose: otherwise use age.
- if needed, repeat dose every 4 hours while symptons last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor

weight (lb)	age	dose (mL or tsp)
under 24	under 2 years	ask a doctor
24 - 35	2 - 3 years	5 mL (1 tsp)
36- 47	4 - 5 years	7.5 mL (1 1/2 tsp)
48 - 59	6 - 8 years	10 mL (10 mL (2 tsp)
60- 71	9 - 10 years	12.5 mg (2 1/2 tsp)
72 95	11 years	15 mL (3 tsp)

use only enclosed dosing cup specfically designed for use with this product

Attention:

use only enclosed dosing cup specfically designed for use with this product

Other information

- each 5 mL (1 tsp) contains: sodium 3 mg
- store between 20-25°C (68-77°F)
- do not refrigerate
- keep carton for complete Drug facts

Inactive ingredients

anhydrous citric acid, butylparaben, FD&C red # 40, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

Questions?

Call 1-877-99-GENOM (43666)

Children's Tukol® Fever Pain product label

Children's Tukol®

Acetaminophen - Pain Reliever-Fever Reducer Oral Suspension

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSION

NEW

Ages 2 - 11

Fever Reducer

Pain Reducer

CHERRY FLAVOR

4 FL OZ (118 mL) 160 mg per 5 mL

Distributer by Genomma Lab USA Inc., Houston, TX 77027

BX--058

LOT No.

Exp.



Oral Suspension

Paracetamol - Analgésico - Antipirético Suspension Oral

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING / NO SE USE SI EL SELLO IMPRESO DEBAJO DE LA TAPA ESTA ROTO O FALTA

Drug Facts (continued)

Attention: use only enclosed dosing our specifical designed for use with this product. So not use any other dosing device.

Other information • each 5 mL (1 bp) contains sodium 3 mg
• store between 20-25°C (68-77°F) • do not refrigerate
• keep carton for complete Drug facts

(Questions? Call 1-877-99-GENOM (43666)

Información del medicamento Ingrediente activo (en cada 5 mL = 1 cucharadita)

racetamol 160 mg.....

USOS temporalmente reduce la fiebre y alivia molestias leves y dolores debidos a: * restific común * gripe * dolor de cabeza * dolor de garganta * dolor de dientes

Advertencias

Advertencia souvra del higado: Este producto contiene achaminente, Parela productiva dalla hepitica grave si su hio tonic: « mala de 5 diose de 24 heres, que si la candidad diase mássima. « one otros tiemacos que centragan acetaminoriemo. Alarta sustenia de control de la missiona de control de la control de la perioriemo del la perioriemo accidencia preguntar a un misidio de farmicio conference accidenciados, preguntar a un misidio de funcione.

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Al usar esta producto, no excende il deles recomendado (vira advertancia de sofernodosio).
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- se prisentam nuevos sintomiss.

- pe prisentam nuevos sintomiss.

Información del medicamento (continuación)

agrano os una arección grave.

Mantáner fuera del alcance de los nillos.

Advarfencia de sobredosis.

En caso de sobredosis. bascar ayuda mádica e
comunicarse con un centro de toxicología de immedian

1-600-222-1222. La altendor médica rápida es

fundamental aunque no se adviertan signos ni sintomas.

- Missifrucciones

 Sale pridecto en confidene instruucciones o advertencias

 Sale pridecto en confidene instruucciones o advertencias
 comprileta para el cuo en adultas.

 Sales instrucción osas.

 Sales ins

peso (lb)	edad (años)	dosis (ml o cdta.)*
menos de 24	menos de 2 años	consultar a un médic
24-35	2-3 años	5 mL (1 cdta.)
36-47	4-5 años	7.5 mL (116 odta.)
48-59	6-8 arios	10 ml, (2 offa.)
60-71	9-10 años	12.5 ml, (2½ odta.)
72-95	11 años	15 mL (3 ofta.)

To según las indicaciones de un médico Atención: Usar solo el viso disaficador adjunto, especificamente diseñado para usar con este producto. No usar ningún otro dispositivo dosificador.

Información adicional

- Cada 5 ni, continente sodio 3 mg
 Aimacenar a a 20-25" C (68-77 °F)
 No refrigerar
 Mantença cajilla para obtener la información del
 Medicamente.
- Ingredientes inactivos

acido citrito anhidro, betiparabeno, rojo altura AC, sabor, glicerina, jarabe de maiz de alta fructiosa, seludiosa misconsistalna y carboximeticelulosa de sodio, propilenglicol, agua purificado, benzosto de sodio, ducido de sorbitol, sucratiosa, goma xantana.

(¿Preguntas? Llame 1-877-99-GENOM (43666)

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8x-osa



2FT_INFYDEWW11



Pain Reliever / Fever reducer Paracetamol Suspensión Oral



160 mg per 5 mL

Drug Facts

Active ingredient (in each 5 mL = 1 teaspoonful)

Description | Pain referent flever reduce

USe's temporarily reduces flever referent min

aches and pains due to: the common cold * flu

headache * sore throat * toothache

Purpose

• headache • sore breast • isomacne
Warnings
Warnings
User semileg the product certains autominished. Severe her damage
no occir if you chief beer, * none than 5 dones in 24 hours, which is the
names cales youth * with the contrasting substancepts.
Allergy silent: Actionished the ground severe your reaction.
Symptoms may rouse * size readers * you?
If you maction occurs, stop use and seek medium * you?
If you maction occurs, stop use and seek medium you got away
Sover through warnings? I save throat it is review prevailed
than 2 days, is accompanied or followed by ferry, headache,
rash nassale or vountifing, consult a colorar principily
Do not use with any other drug containing acetamisophen
prescription or nosprescription! If you are not sure whether a
drug contains acchaminopher, ask a doctor or pharmacist.
Asik a doctor before use if the child has liver disease.

Ask a doctor before use if the child has it Ask a doctor or pharmacist before use if the child is taking the blood thinning drug warfanin

When using this product do not exceed recordose (see overdose warning)

soble piece orbinologe waterings:

Stop use and asix a doctor if — pain gets worse or lasts
more than 5 days — feere gets worse or lasts more than 3 days
— new symptoms occur — redness or swelling is present.
These council or eighing of a serious condition.
Kacep out of reach of children.
Oversidose waterings in case of oversidose, get medical holp or
contact a Pracon Control Center (1-800-202) 12020 regist away.
Duck, medical alterston is critical — even if you do not notice
any signs or symptoms.

- any signs or symptoms.

 Directions **

 product is not labeled with directions or complete warnings for adult use *

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LOT No. / LOTE. Eq./Eq.



Consulte el cartón para la información del medicamento completo

Información del medicamento Ingrediente Activo(en cada 5 mL = 1 cucharadita)
Paracetamol 160 mg.

Usos • temporalmente reduce la fiebre y alvia molestias leves y dulores debido ac • restriado común • gripe • dolar de cabeza • dolar de garganta • dolar de clientes

Advertencias

Advertiencia soerca del higado: Este producto contiene acetaminofeno. Puede productiva dallo hepistico prese su bijo harma: « nato del 5 costo en 24 hiesto, que es la cantidad danta misema» con crisco fiarmaciós que contrengon acetamisefeno. Alerta sobre allergia. El acetaminofeno puede previocar rescolares graves en la piet. Es sistemas puedes incluir » empisionante de la piet » ampellas » sarpullato. Si se produce una sección en la piet a superior el calcur y buscar ayesta medica de immediato. Alertancia acerca del delere de garganta: Si el sister de garganta es obreso, persobe per nato de 2 días, está acompolístic o seguidos de facte, dobre o ciudeza, sarpuldiós, rabusas o visimitos, comunitar a un médico de immediato. No usar « Can emplia dos faminacio persona para acetaminofeno precisido o de verta librei. Si no se está seguio si el faminacio portene acetaminofeno, preguntar a un medico de la verta librei. Si no se está seguio si el faminacio portene acetaminofeno, preguntar a un medico de la contracicação.

Balantere fuera del alcance de los elibro. Advertincia de sobredosis. En caso de sobredosis, buscar ayudo, medica o contracioses con un centro de texinólogo de emediato (1-900-222-1222). La asercidon médica

médica o comunicarse con un centro de toxicologia de inmediato (1-800-2221-222). La atención médica ricoda es trademental aumpa no se adelentar signas ni sintomas.

Instrucciones - Este producto no confiner instrucciones o advertencias completas para el uso en adultos. - Agitar bien antes de usar - mi. — mililitro: cdta — cucharadita - Buscar la dosis correcta en el siguiente cuadro. De ser posible, usar el peso gara la dosis; de lo contrario, usar la dedid. - De ser necesario, repetir la dosis cada 4 oras mientras perduren los sintomas. - No administrar más de 5 veces en 24. horas. • No administrar durante más de 5 días a menos que lo indique un médico.

peso (b)	edad (años)	dosis (ml. or odta.)*
menos de 24	menos de 2 años	consultar a un médico
24-35	2-3 años	5 mL (1 cdta.)
36-47	4-5 años	7.5 mL (1½ cdta.)
48-59	6-8 años	10 mL (2 cdta.)
60-71	9-10 años	12.5 mL (2½ cdta.)
72-95	11 años	15 mL (3 cdta.)

Información adicional • cada 5 ml. (1 tsp) contienen: sodio 3 mg •

(¿Preguntas? Llame 1-877-99-GENOM (43666)

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DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING / NO SE USE SI EL SELLO IMPRESO DERAJO DE LA TAPA ESTA ROTO O FALTA

Refer to carton for complete drug fact information

Active ingredient (in each 5 mL = 1 teaspoon) Purpose hen 160 mg.,

Uses temporarily • reduces fever • relieves minor aches and pains due to: . the common cold . flu . headache . sore throat . toothache

Warnings

Uver warning: This product contains acetaminophen, Severe liver damage may occur
if your child takes: * more than 5 doses in 24 hours, which is the maximum daily amount
* with other drugs containing acetaminophen. Altergy alert. Acetaminophen may cause
severe skin reactions. Symptoms may include: * skin reddening * blisters * rash.
If skin reaction occurs, stop use and seek medical help night away. Sore Broat
if skin reaction occurs, stop use and seek medical help night away. Sore Broat
for short of the stop of the sto

Social or pnarmacist.

Keep out of reach of children, in case of overdose, per medical help or contact a Poison Control
Center (1-800-222-1222) right away. Quick medical attention is critical. even if you do not notice
any signs or symptoms.

Directions • this product does not contain directions or complete warnings for adult use, • shake well before using • ml, • millitier; tsp • tesspoonful • fed right does on chart below. If possible, use weight to dose, otherwise, use age. • if needed, repeat dose every 4 hours while symptoms last • do not give more than 5 times in 24 hours • do not give for more than 5 days unless directed by a doctor

weight (lb)	age (yr)	dose (mL or tsp)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 ml. (1 tsp)
36-47	4-5 years	7.5 ml. (1½ tsp)
48-59	6-8 years	10 mL (2 tsp)
60-71	9 10 years	12.5 mL (2% tsp)
72-95	11 years	15 mL (3 tsp)

Other information • each 5 mL (1 tsp) contains: sodium 3 mg • store n 20-25°C (68-77°F) • do not refrigerat

(Questions? Call 1-877-99-GENOM (43666)

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DO NOT USE IF PRINTED NECKRAND IS BROKEN OR MISSING / NO SE USE SI EL SELLO IMPRESO DEBAJO DE LA TAPA ESTA ROTO O FALTA LR-086



CHILDRENS TUKOL ACETAMINOPHEN FEVER REDUCER PAIN REDUCER

acetaminophen liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-525
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients		
In	igredient Name	Strength
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
BUTYLPARABEN (UNII: 3QPI1U3FV8)		

, , ,	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Pac	kaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NI	DC:50066-525-24	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2016	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part343	05/03/2016		

Labeler - Genomma Lab USA, Inc. (832323534)

Registrant - AptaPharma Inc. (790523323)

Establishment			
Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(50066-525)

Revised: 4/2017 Genomma Lab USA, Inc.