

**DICLOFENAC SODIUM TOPICAL 1%- diclofenac sodium gel**  
**YYBA CORP**

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**YYBA (as PLD) - Welmate Diclofenac Sodium Topical Gel, 1% (73581-104)**

**Active ingredient**

DICLOFENAC SODIUM (NSAID\*) 1% (EQUIVALENT TO 0.93% DICLOFENAC)

\*NONSTEROIDAL ANTI-INFLAMMATORY DRUG

**Purpose**

ARTHRITIS PAIN RELIEVER

**Uses**

- FOR THE TEMPORARY RELIEF OF ARTHRITIS PAIN ONLY IN THE FOLLOWING AREAS:
- HAND, WRIST, ELBOW (UPPER BODY AREAS)
- FOOT, ANKLE, KNEEW (LOWER BODY AREAS)
- THIS PRODUCT MAY TAKE UP TO 7 DAYS TO WORK FOR ARTHRITIS PAIN; IT IS NOT FOR IMMEDIATE RELIEF. IF NO PAIN IN 7 DAYS, STOP USE.

**Warnings**

FOR EXTERNAL USE ONLY.

ALLERGY ALERT: DICLOFENAC MAY CAUSE A SEVERE ALLERGIC REACTION, ESPECIALLY IN PEOPLE ALLERGIC TO ASPIRIN. SYMPTOMS MAY INCLUDE:

- HIVES
- ASTHMA (WHEEZING)
- SKIN REDDENING
- BLISTERS
- FACIAL SWELLING
- SHOCK
- RASH

IF ALLERGIC REACTION OCCURS, STOP USING AND SEEK MEDICAL HELP RIGHT AWAY.

LIVER WARNING: THIS PRODUCT CONTAINS DICLOFENAC. LIVER DAMAGE MAY OCCUR IF YOU APPLY

- MORE OR FOR A LONGER TIME THAN DIRECTED.
- WHEN USING OTHER DRUGS CONTAINING DICLOFENAC

STOMACH BLEEDING WARNING: THIS PRODUCT CONTAINS AN NSAID, WHICH MAY CAUSE SEVERE STOMACH BLEEDING. THE CHANCE IS SMALL BUT HIGHER IF YOU

- ARE AGE 60 OR OLDER
- HAVE HAD STOMACH ULCERS OR BLEEDING PROBLEMS

- TAKE A BLOOD THINNING (ANTICOAGULANT) OR STEAROID DRUGS
- TAKE OTHER DRUGS CONTAINING PRESCRIPTION OR NONPRESCRIPTION NSAIDS (ASPIRIN, IBUPROFEN, NAPROXEN, OR OTHERS)
- HAVE 3 OR MORE ALCOHOLIC DRINKS EVERY DAY WHILE USING THIS PRODUCT
- APPLY MORE OR FOR LONGER THAN DIRECTED

HEART ATTACK AND STROKE WARNING: NSAIDS, EXCEPT ASPIRIN, INCREASE THE RISK OF HEART ATTACK, HEART FAILURE, AND STROKE. THESE CAN BE FATAL. THE RISK IS HIGHER IF YOU USE MORE THAN DIRECTED OR FOR LONGER THAN DIRECTED.

#### DO NOT USE

- IF YOU HAVE EVER HAD AN ALLERGIC REACTION TO ANY OTHER PAIN RELIEVER OR TO A FEVER REDUCER
- FOR STRAINS, SPRAINS, BRUISES OR SPORTS INJURIES. THIS PRODUCT HAS NOT BEEN SHOWN TO WORK FOR THESE TYPES OF INJUTIRES
- RIGHT BEFORE OR AFTER HEART SURGERY
- ON MORE THAN 2 BODY AREAS AT THE SAME TIME
- IN THE EYES, NOSE OR MOUTH

#### ASK A DOCTOR BEFORE USE IF

- YOU HAVE PROBLEMS OR SERIOUS SIDE EFFECTS FROM TAKING PAIN RELIEVERS OR FEVER REDUCERS
- STOMACH BLEEDING WARNING APPLIES TO YOU
- YOU HAVE A HISTORY OF STOMACH PROBLEMS, SUCH AS HEARTBURN
- YOU HAVE HIGH BLOOD PRESSURE, HEART DISEASE, LIVER CIRRHOSIS, KIDNEY DISEASE, ASTHMA, OR HAD A STROKE
- YOU ARE TAKING A DIURETIC
- YOU ARE UNDER AGE 18 YEARS. IT IS NOT KNOWN IF THIS DRUG WORKS OR IS SAFE IN CHILDREN UNDER AGE 18 YEARS.

#### ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE

- UNDER A DOCTOR'S CARE FOR ANY SERIOUS CONDITION
- TAKING ANY OTHER DRUG

#### WHEN USING THIS PRODUCT

- AVOID CONTACT WITH EYES, NOSE, OR MOUTH
- IF EYE CONTACT OCCURS, RINSE THOROUGHLY WITH WATER

#### STOP USE AND ASK A DOCTOR IF

- PAIN GETS WORSE OR LASTS MORE THAN 21 DAYS
- REDNESS OR SWELLING IS PRESENT IN THE PAINFUL AREA
- FEVER OCCURS
- SKIN IRRITATION OCCURS
- ANY NEW SYMPTOMS APPEAR. THESE COULD BE SIGNS OF A SERIOUS CONDITION.
- YOU EXPERIENCE ANY OF THE FOLLOWING SIGNS OF STOMACH BLEEDING:
  - FEEL FAINT
  - HAVE BLOODY OR BLACK STOOLS
  - VOMIT BLOOD
  - HAVE STOMACH PAIN THAT DOES NOT GET BETTER
- IF YOU HAVE SYMPTOMS OF HEART PROBLEMS OR STROKE:

- CHEST PAIN
- TROUBLE BREATHING
- LEG SWELLING
- WEAKNESS IN ONE PART OR SIDE OF BODY
- SLURRED SPEECH

IF PREGNANT OR BREAST-FEEDING, ASK A HEALTH PROFESSIONAL BEFORE USE. IT IS ESPECIALLY IMPORTANT NOT TO USE DICLOFENAC AT 20 WEEKS OR LATER IN PREGNANCY UNLESS DEFINITELY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER (1-800-222-1222) RIGHT AWAY.

## Directions

USE UP TO 21 DAYS UNLESS DIRECTED BY YOUR DOCTOR.

NOT FOR STRAINS, SPRAINS, BRUISES, OR SPORTS INJURIES. THIS PRODUCT HAS NOT BEEN SHOWN TO WORK FOR THESE TYPES OF INJURIES.

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DAILY	PER DOSE
FOR YOUR ARTHRITIS PAIN:	USE ENCLOSED DOSING CARD TO MEASURE A
• USE 4 TIMES PER DAY EVERY DAY	DOSE
• DO NOT USE ON MORE THAN 2 BODY AREAS AT THE SAME TIME	<ul style="list-style-type: none"> <li>• FOR EACH UPPER BODY AREA (HAND, WRIST, OR ELBOW) - SQUEEZE OUT 2.25 INCHES (2 GRAMS)</li> <li>• FOR EACH LOWER BODY AREA (FOOT ANKLE, OR KNEE) - SQUEEZE OUT 4.5 INCHES (4 GRAMS)</li> </ul>

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READ THE ENCLOSED USER GUIDE FOR COMPLETE INSTRUCTIONS:

- USE ONLY AS DIRECTED
- DO NOT USE MORE THAN DIRECTED OR FOR LONGER THAN DIRECTED
- APPLY ONLY TO CLEAN, DRY SKIN THAT DOES NOT HAVE ANY CUTS, OPEN WOUNDS, INFECTIONS, OR RASHES
- DO NOT APPLY IN SAME AREA AS ANY OTHER PRODUCT
- DO NOT APPLY WITH EXTERNAL HEAT SUCH AS A HEATING PAD
- DO NOT APPLY A BANDAGE OVER THE TREATED AREA
- STORE ENCLOSED DOSING CARD WITH YOUR DICLOFENAC SODIUM TOPICAL GEL, 1%. THE DOSING CARD IS RE-USABLE.

## OTHER INFORMATION


- STORE AT 20-25°C (68-77°F). KEEP FROM FREEZING.
- READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THE DOSING CARD, THIS CARTON AND ACCOMPANYING USER GUIDE FOR IMPORTANT INFORMATION.

## INACTIVE INGREDIENTS

CARBOMER HOMOPOLYMER TYPE C, COCOYL CAPRYLOCAPRATE, ISOPROPYL ALCOHOL, MINERAL OIL, POLYOXYL 20 CETOSTEARYL ETHER, PROPYLENE GLYCOL, PURIFIED WATER, AND STRONG AMMONIA SOLUTION.

## QUESTIONS OR COMMENTS?

1-866-933-6337



Compare to the active ingredient in  
**Voltaren Arthritis Pain Gel\*\***

**ORIGINAL PRESCRIPTION STRENGTH**

**Diclofenac Sodium Topical Gel, 1%**  
(NSAID) - Arthritis Pain Reliever







NET WT 5.29 oz (150 g)

**For external use only**

**Clinically Proven to Relieve Arthritis Pain**

**Medicated Gel**  
**Clinically Proven to**  
**Relieve Arthritis**  
**Pain**

**TREATMENT AREAS**

Not for use on any other body area (such as back, hip, or shoulder)

Code: GO/DRUGS/361

Distributed by: **Wellspring**  
Airmont, NY 10952, U.S.A.

\*\*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, PLC, distributor of Voltaren Arthritis Pain Gel.

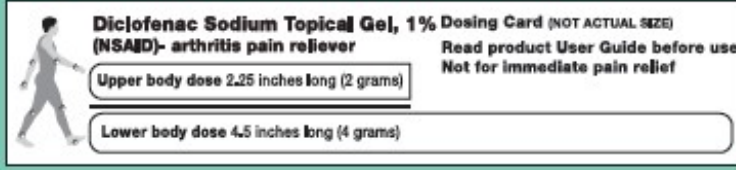
<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> Diclofenac sodium (NSAID)* 1% (equivalent to 0.99% diclofenac)</p> <p><b>Purpose</b> Arthritis pain reliever</p> <p><b>Uses</b>  <ul style="list-style-type: none"> <li>■ for the temporary relief of arthritis pain ONLY in the following areas:               <ul style="list-style-type: none"> <li>■ hand, wrist, elbow (upper body areas)</li> <li>■ foot, ankle, knee (lower body areas)</li> </ul> </li> <li>■ this product may take up to 7 days to work for arthritis pain; it is not for immediate relief.</li> <li>■ no pain relief in 7 days, stop use.</li> </ul> </p> <p><b>Warnings</b>  <b>For external use only</b>  <b>Allergy alert:</b> Diclofenac may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:  <ul style="list-style-type: none"> <li>■ hives</li> <li>■ asthma (wheezing)</li> <li>■ skin reddening</li> <li>■ blisters</li> <li>■ facial swelling</li> <li>■ shock</li> <li>■ rash</li> </ul>           If an allergic reaction occurs, stop use and seek medical help right away.         </p>	<p><b>Drug Facts (continued)</b></p> <p><b>Liver warning:</b> This product contains diclofenac. Liver damage may occur if you apply:  <ul style="list-style-type: none"> <li>■ more or for a longer time than directed</li> <li>■ when using other drugs containing diclofenac</li> </ul> </p> <p><b>Stomach bleeding warning:</b> This product contains an NSAID, which may cause severe stomach bleeding. The chance is small but higher if you:  <ul style="list-style-type: none"> <li>■ are age 60 or older</li> <li>■ have had stomach ulcers or bleeding problems</li> <li>■ take a blood thinning (anticoagulant) or steroid drug</li> <li>■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)</li> <li>■ have 3 or more alcoholic drinks every day while using this product</li> <li>■ apply more or for longer than directed</li> </ul> </p> <p><b>Heart attack and stroke warning:</b> NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.</p>
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LIFT FLAP FOR IMPORTANT DIRECTIONS & WARNINGS

<p><b>Drug Facts (continued)</b></p> <p><b>Do not use</b>  <ul style="list-style-type: none"> <li>■ if you have ever had an allergic reaction to any other pain reliever or to a fever reducer</li> <li>■ for strains, sprains, bruises or sports injuries. This product has not been shown to work for these types of injuries</li> <li>■ right before or after heart surgery</li> <li>■ on more than 2 body areas at the same time</li> <li>■ in the eyes, nose or mouth</li> </ul> </p> <p><b>Ask a doctor before use if</b>  <ul style="list-style-type: none"> <li>■ you have problems or serious side effects from taking pain relievers or fever reducers</li> <li>■ stomach bleeding warning applies to you</li> <li>■ you have a history of stomach problems, such as heartburn</li> <li>■ you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke</li> <li>■ you are taking a diuretic</li> <li>■ you are under age 18 years. It is not known if this drug works or is safe in children under age 18 years.</li> </ul> </p>	<p><b>Drug Facts (continued)</b></p> <p><b>Ask a doctor or pharmacist before use if you are</b>  <ul style="list-style-type: none"> <li>■ under a doctor's care for any serious condition</li> <li>■ taking any other drug</li> </ul> </p> <p><b>When using this product</b>  <ul style="list-style-type: none"> <li>■ avoid contact with eyes, nose, or mouth</li> <li>■ if eye contact occurs, rinse thoroughly with water</li> </ul> </p> <p><b>Stop use and ask a doctor if</b>  <ul style="list-style-type: none"> <li>■ pain gets worse or lasts more than 21 days</li> <li>■ redness or swelling is present in the painful area</li> <li>■ fever occurs</li> <li>■ skin irritation occurs</li> <li>■ any new symptoms appear. These could be signs of a serious condition.</li> </ul> </p> <p><b>You experience any of the following signs of stomach bleeding:</b>  <ul style="list-style-type: none"> <li>■ feel faint</li> <li>■ have bloody or black stools</li> <li>■ vomit blood</li> <li>■ have stomach pain that does not get better</li> </ul> </p> <p><b>you have symptoms of heart problems or stroke:</b>  <ul style="list-style-type: none"> <li>■ chest pain</li> <li>■ trouble breathing</li> <li>■ leg swelling</li> <li>■ weakness in one part or side of body</li> <li>■ slurred speech</li> </ul> </p>
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<p><b>Drug Facts (continued)</b></p> <p>■ <b>pregnant or breast-feeding</b>, ask a health professional before use. It is especially important not to use diclofenac at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center (1-800-232-1222) right away.</p>		<p><b>Drug Facts (continued)</b></p> <p><b>Read the enclosed User Guide for complete instructions:</b></p> <ul style="list-style-type: none"> <li>■ use only as directed</li> <li>■ do not use more than directed or for longer than directed</li> <li>■ apply only to clean, dry skin that does not have any cuts, open wounds, infections or rashes</li> <li>■ do not apply in same area as any other product</li> <li>■ do not apply with external heat such as heating pad</li> <li>■ do not apply a bandage over the treated area</li> <li>■ store ENCLOSED DOSING CARD with your Diclofenac Sodium Topical Gel, 1%. The dosing card is re-usable.</li> </ul>	
<p><b>Directions</b></p> <p>Use up to 21 days unless directed by your doctor.</p> <p>Not for strains, sprains, bruises or sports injuries. This product has not been shown to work for these types of injuries.</p>		<p><b>Other Information</b></p> <ul style="list-style-type: none"> <li>■ Store at 20-25°C (68-77°F). Keep from freezing.</li> <li>■ read all product information before using. Keep the dosing card, this carton and accompanying User Guide for important information.</li> </ul>	
<p><b>Daily</b></p> <p>For your arthritis pain:</p> <ul style="list-style-type: none"> <li>■ Use 4 times per day every day</li> <li>■ Do not use on more than 2 body areas at the same time</li> </ul>	<p><b>Per Dose</b></p> <p>Use ENCLOSED DOSING CARD to measure a dose</p> <ul style="list-style-type: none"> <li>■ For each upper body area (hand, wrist, or elbow)—Squeeze out 2.25 inches (2 grams)</li> <li>■ For each lower body area (foot, ankle or knee)—Squeeze out 4.5 inches (4 grams)</li> </ul>	<p><b>Inactive ingredients</b> carbomer homopolymer Type C, cocoyl caprylocaprates, isopropyl alcohol, mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, and strong ammonia solution.</p> <p><b>Questions or comments? 1-866-933-6337</b></p>	

### Use Enclosed Dosing Card to Measure a Dose



**Diclofenac Sodium Topical Gel, 1% Dosing Card (NOT ACTUAL SIZE)**  
(NSAID)- arthritis pain reliever

Read product User Guide before use  
Not for immediate pain relief

Upper body dose 2.25 inches long (2 grams)

Lower body dose 4.5 inches long (4 grams)

**Tamper evident statement: Do not use if safety seal on tube nozzle is broken or missing.**

### How to Use

- For arthritis pain only
- Use 4 times a day
- May take up to 7 days to work for your arthritis pain
- For use on no more than 2 body areas
- Use up to 21 days unless directed by your doctor

## Medicated Gel Clinically Proven to Relieve Arthritis Pain

### TREATMENT AREAS



Not for use on any other body area (such as back, hip, or shoulder)

\*\*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, PLC, distributor of Voltaren Arthritis Pain Gel.

Code: GO/DRUGS/361      Distributed by: **WellSpring** Airmont, NY 10952, U.S.A.

<b>DICLOFENAC SODIUM TOPICAL 1%</b>			
diclofenac sodium gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73581-104
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:144O8QL0L1)	DICLOFENAC SODIUM	1 mg in 100 g
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	WATER (UNII: 059QF0KO0R)		
	CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)		
	COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)		
	ISOPROPYL ALCOHOL (UNII: ND2M41630Z)		
	MINERAL OIL (UNII: T5L8T28FGP)		
	POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)		
	AMMONIA (UNII: 5138Q19F1X)		

**PROPYLENE GLYCOL (UNII: 6DC9Q167V3)**

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73581-104-15	1 in 1 BOX	08/31/2023	
1		150 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210986	08/31/2023	

**Labeler - YBBA CORP (006339772)**

Revised: 1/2024

YBBA CORP