HIGHLIGH S OF PRESCRIBING INFORMAT ON

hese highlights do not include all the information needed to use DICLOFENAC POTASSIUM for ORAL SOLUT ON safely and effectively. See full prescribing information for DICLOFENAC POTASSIUM for ORAL SOLUT ON.

DICLOFENAC POTASSIUM for oral solution
Initial U.S. Appro a : 988

WARN NG: RISK OF SER OUS CARDIOVASCULAR AND GAS RO N ES INAL EVEN S
See u l prescr b ng information or comp ete boxed warning

Cardiovascular Risk

- Non-s eroidal anti-inflammatory d ugs (NSAIDs) may inc ease he r sk of serious ca diovascu ar (CV) thrombot c events, myocard al infarc ion, and stroke, which can be fatal. Risk may increase w th du at on of use. (5.1)
- Diclofenac Potass um for Oral Solut on s contraind cated for he reatment of peri-opera ive pain in he sett ng of coronary artery bypass graft (CABG) surgery. (4, 5.1)

Gastrointest nal Risk

- NSAIDs ncrease he risk of serious gastrointest nal (GI) adverse events inc uding b eeding, ulce at on, and perforat on of the stomach or intest nes, which can be fatal. Events can occur at any time without warn ng symptoms. E derly pa ients are at g eater r sk. (5 2)

NDICA IONS AND USAGE

D c ofenac Potass um for Oral Solu ion s a non-stero dal anti- nflammato y (NSAID) drug indicated for the acute treatment of migraine attacks w th or without au a in adu ts 18 years of age or older (1 1)

Impor ant Limitat ons (1.2):

- Diclo enac Potass um or Oral Solution is not indicated for the prophylact c therapy of migraine
- Sa ety and effec iveness of D c o enac Potass um for Oral Solution not estab ished for cluster headache, wh ch s present n an o der, predominantly male populat on

DOSAGE AND ADMINIS RA ION

S ngle 50 mg dose; mix sing e packet contents wi h 1 to 2 ounces (30 to 60 mL) of wa er pr or to adm n s ra ion (1)

DOSAGE FORMS AND S RENG HS

Packets: Each con a n ng wh te to o f-wh te, flavored powder of dic ofenac potassium 50 mg in a so uble powder (3)

CON RAINDICA IONS

- Known hypersensit v ty to d c ofenac or NSAIDs (4)
- Pre-existing asthma, ur icar a, or a lergic-type reactions after aking asp rin or other NSAIDs (4)
- Use dur ng the peri-opera ive period n the setting of coronary ar ery bypass gra t (CABG) surgery (4, 5 1)

WARN NGS AND PRECAU ONS

- Serious and potent a ly fatal CV th ombot c events: Use lowest effec ive dose of Diclofenac Po assium or O al Solution or shor est possible duration (5 1)
- Se ious and po ential y fa al GI react ons: Use owest effect ve dose of Diclo enac Potass um for Oral Solut on for shortest possible durat on; use w th cau ion n patien s with prior history of ulcer d sease or GI b eed ng (5.2)
- Hepa ic e fects: Range from transam nase elevat ons to iver failure; discon inue Diclofenac Po assium or O al Solution mmediate y if abnormal l ver ests persist or worsen (5.3, 5.13)
- Hype tension: Can occur with NSAID trea ment. Moni or blood p essure close y du ing reatment w th Diclofenac Potassium for Oral So ut on (5.4)
- Congestive heart a lure and edema: Fluid retention and edema can occur with NSAID treatment; use D c ofenac Potassium for Oral So ut on w th caut on n pa ients w th fluid retent on or heart a lure (5.5)
- Renal effects: Long-te m adm n st at on of NSA Ds can result n enal pap l ary necros s and other renal inju y; use D c o enac Potassium for O al So ut on wi h caution n pat ents at risk (e g., the elder y, those w th renal impai ment, heart fa lure, iver impairment, and those tak ng d u et cs or ACE nhibitors) (5.6)
- Anaphylacto d react ons: May occur in patients w th the aspir n tr ad or n pat ents without prior exposure to Diclofenac Potass um for Oral Solution; d scontinue D c ofenac Potassium for O al So ut on immediately if an anaphy actoid reaction occurs (5.7)
- Serious skin react ons: Include ex o iative dermatit s, S evens-Johnson Synd ome, and tox c epide mal necro ys s, which can be fatal; discon inue Diclofenac Potassium or Oral Solution if rash or other signs of local skin reaction occur (5.8)

ADVERSE REAC IONS

Most common adve se react ons (≥1% and >placebo) were nausea and d zz ness (6 1)

o report SUSPEC ED ADVERSE REAC IONS contact Par Pharmaceu ical Inc at 1 800 828 9393 or FDA at 1 800 FDA 1088 or www fda gov/medwatch

DRUG IN ERAC IONS

- Aspir n: Concomitant administration w th other NSA Ds, inc uding asp rin, is not ecommended because of an inc eased risk of adverse react ons, inc uding GI bleeding (7 1)
- An icoagulan s: Concomitant use of diclofenac and an icoagulants (e.g., war ar n) increases the r sk of ser ous GI bleeding (7.2)

USE IN SPECIFIC POPULA IONS

- Pregnancy: Based on an mal data, may cause fetal harm. Based on human da a, s art ng at 30 weeks gestat on, D c ofenac Potassium for Oral Solution should be avoided as premature closure of the ductus arter osus n the fetus may occur (5.9, 8.1)
- Nurs ng Mo hers: Use with caut on, as it is not known if d c o enac s exc eted in human m lk (8.3)
- Hepatic nsu ficiency: The iver metabol zes almost 100% of d c ofenac; there is nsu ficient informat on avai able to suppo t dosing recommenda ions or Diclofenac Potassium for O al Solution in pa ients with hepa ic insuffic ency (5.3, 8.6, 12.3)

See 17 for PA EN COUNSELING NFORMA ION and Medication Guide

Issued: 07/2015

FULL PRESCRIBING INFORMAT ON: CON ENTS*

WARNING: RISK OF SER OUS C RDIOV SCULAR AND GAS ROIN ES INAL EVENTS

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*** Sections or subsections omitted from the fu l prescr bing information are not listed**

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FULL PRESCRIBING INFORMAT ON

WARNING: R SK OF SERIOUS CARDIOVASCULAR AND GASTROIN ES INAL E EN S

Cardio ascular Risk

- **Non steroidal anti inflammatory drugs (NS IDs) may increase the risk of serious cardio ascular (CV) thrombotic e ents, myocardial infarc ion, and stroke, which can be fatal. his risk may inc ease with duration of use. Patients with cardio ascular disease or risk factors for car io ascular isease may be at greater risk *[see* Warn ngs and Precautions (5 1)*]*.**
- **Diclofenac Potassium for Oral Solution is contrain icated for the treatment of peri operative pain in the setting of coronary artery bypass graft (CABG) surgery *[see* CON RAINDICA IONS (4) *and* Warn ngs and Precautions (5 1)*]*.**

Gastrointestinal Risk

- **NSA Ds increase the risk of serious gastrointes inal (GI) ad erse events inclu ing bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. hese e ents can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal e ents *[see* Warn ngs and Precautions (5 2)*]*.**

1 IND CAT ONS AND US GE

1.1 Acute Treatment of Migraine

c of ac otass m fo a So to s d cat d fo t ac t t atm t of m g a attac s wt o wt o t a a ad s 8 y a s of ag o o d

1.2 Impor ant Limitations

- c of ac otass m o a So to s ot d cat d fo t p op y act c t a y of m g a
- saf ty a d ff ct v ss of c of ac otass m fo a So to av ot b s ab s d fo c st adac w c sp s t a o d p dom a ty ma pop ato

2 DOS GE AND ADMINIS RA ION

2.1 Acute Treatment of Migraine

dm st o pac t 50 mg of c of ac otass m fo a So to fo t ac t t atm t of m g a mpty t co t ts of o pac t to a c p co ta g o 2 o c s 30 to 60 m of wat m x w a d d mm d at y o ot s q ds ot t a wat

a g c of ac o ass m fo a So to wt ood may ca s a d cto f ct v ss compa d to ta g c of ac otass m fo a So to o a mpty s omac *[see* **C in cal Pharmacology (12 3)***]*

Us t ow st ff ct v dos o t s ot st d ato co sst t wt d v d a pat t t atm t goa s saf ty a d f ct v ss of a s co d dos av ot b stab s d

2.2 Conversion From Other Formulations of Diclofenac

ff t fo m ato s of o a d c of ac g c of ac otass m fo a So to d c of ac sod m t c coat d tab s d c of ac sod m xt d d as tab s o d c of ac potass m mm d at as tab s may ot b b o q va t v ft m g am st gt st sam o t s ot poss b to co v t dos g f om a y ot fo m ato of d c of ac o c of ac o ass m fo a So to

3 DOS GE FORMS AND STRENGTHS

c of ac otass m fo a So to s ava ab d v d a pac s ac d s g d to d v a 50 mg dos w m x d wat

4 CONTRAINDICAT ONS

c of ac otass m fo a So to s co t a d cat d pat ts wt ow yp s st v ty g a ap y ac o d act o s a d s o s s act o s to d c of ac *[see* **Warnings and Precautions (5 7 5 8)***]*

c of ac otass m fo a So to s co t a d cat d pat ts w o av xp c d ast ma t ca a o a g c typ act o s aft a g asp o ot NS I s S v som t m s fa a a ap y act c act o s o NS I s av b po t d s c pat ts *[see* **Warnings and Precautions (5 7 5 12)***]*

c of ac otass m fo a So to s co t a d cat d fo t t atm t of p op at v pa t s t g of co o a y a t y bypass g aft s g y *[see* **Warnings and Precautions (5 1)***]*

5 WARNINGS AND PRECAUTIONS

5.1 Car iovascular hrombotic Events

ca t as of s v a X 2 s ct v a d o s ct v NS I s of p to t y a s d ato av s ow a c as d s of s o s ca d ovasc a V t ombot c v ts myoca d a fa cto a d st o w c ca b fata NS I s bot X 2 s ct v a d o s ct v may av as m a s at ts wt ow V d s as o s acto s fo V d s as may b at g at s om m z t pot ta s fo a adv s V v t pat ts t at d wt a NS I s t ow st f ct v dos fo t s ot st d ato poss b ys ca s a d pat ts s o d ma a t o t d v opm t of s c v ts v t abs c of p vo s V symptoms I o m pat ts abo t t s g s a d symptoms of s o s V v ts a d t st ps to a ft y occ

s o co sst t v d c t at co c t s of asp m t gat st c as d s of s o s Vt ombot c v s assoc at d wt NS I s co c t s of asp a d a NS I c as s t s of s o s I v s *[see* **Warnings and Precau ions 5 2)***]*.

wo a g co to d c ca t as of a X 2 s ct v NS I fo t t atm t of pa t fi st 0 to days fo ow g co o a y a t y bypass g a t s g y fo d a c as d c d c of myoca d a fa cto a d st o *[see* **CON RAINDICA IONS (4)***]*.

5.2 Gastrointestinal Effects - Risk of Ulceration, Bleeding, and Perforation

NS I s c d g c of ac otass m fo a So to ca ca s s o s gast o t st a I adv s v ts s c as flammat o b d g c ato a d p fo ato of t stomac sma t st o a g t st w c ca b fata s s o s adv s v s ca occ at a y t m wt o wt o t wa g symptoms pat ts t at d wt NS I s y o fiv pat ts w o d v op a s o s pp I adv s v to NS I t apy s symptomat c Upp I c s g oss b d g o p o ato ca s d y NS I s occ app ox mat y % of pat ts t at d fo 3 to 6 mo t s a d abo t 2% to % of pat ts t at d fo o y a s t ds co t wt o g d ato of s t s c as g t ood of d v op g a s o s I v t at som t m d g t co s of t apy ow v v s o t t m NS I t apy s ot wt o t s

sc b NS I s c d g c of ac o ass m o a So to wt xt m ca to pat s wt a p o sto y of c d s as o I b d g at ts wt a p o sto y of p ptc c d s as a d/o gast o t st a b d g w o s NS I s av a g at t a 0 od s fo d v op g a I b d t a pat ts wt t of t s s facto s t facto s t at c as t s fo I b d g pat ts t at d wt NS I s c d co com a t s of o a co t cost o ds o a t coag a s o g d ato of NS I t apy smo g s of a co o o d ag a d poo g a at s at s Most spo ta o s po ts of fata I v ts a d y o d b tat d pat ts a d t o sp ca ca s o d b ta t at g t s pop ato

o m m z t pot ta s fo a adv s I v t pat ts t at d wt a NS I s t ow st ff ct v dos o t s ot st poss b d ato at ts a d p ys ca s s o d ma a t fo s g s a d symptoms of I c ato a d b d g d g c of ac otass m fo a So to t a y a d p ompt y tat add to a va ato a d t atm t f as o s I adv s v t s s sp ct d s s o d c d d sco t ato of t c of ac otass m o a So to t as o s I adv s v t s d o t o g s pat s at at v t ap s t at do ot c d NS I s s o d b co s d d

5.3 Hepatic Effects

vat o s of o o mo v t s s may occ d g t apy wt c of ac o ass m fo a So to s abo ato y ab o ma t s may p og ss may p sst o may o y b t a s t wt co t d t apy o d vat o s ss t a 3 t m s t pp m t of t o ma [U N] a g o g at vat o s of t a sam as s occ d abo t 5% of d c of ac t at d pat ts f t ma s of pat c f cto S s comm d d o t mo to g of v y

I c ca t as m a gf vat o s mo t a 3 t m s t U N of S S occ d abo t 2% of app ox mat y 5 00 pat ts at som t m d g t atm t was ot m as d a st d s I a op ab co t o d t a of 3 00 pat ts t at d fo 2 to 6 mo t s pat s w mo o d at 8 w s a d 200 pat ts w mo to d aga at 2 w s M a gf vat o s of a d/o S occ d abo t % of t 3 00 pat ts a d c d d ma d vat o s 8 t m s t U N abo t % of t 3 00 pat ts I t s op ab st dy a g c d c of bo d ss t a 3 t m s t U N mod at 3 o 8 t m s t U N a d ma d 8 t m s t U N vat o s of o S was obs v d pat ts c v g d c of ac w compa d to ot NS I s most a m a gf vat o s t a sam as s w d t ct d b o pat ts b cam symptomat c

b o ma t sts occ d d g t fi st 2 mo t s of t apy wt d c of ac 2 of t 5 pat ts a t as w o d v op d ma d t a sam as vat o s I postma t g po ts cas s of d g d c d patotox c ty av b po t d t fi st mo t a d som cas s t fi st 2 mo t s of NS I t apy b t ca occ at a y t m d g t atm t wt d c of ac

ostma t g s v a c as po t d cas s of s v pat c act o s c d g v c oss a d c f m a t pat t s wt a d wt o t a d c a d v fa Som of t s po t d cas s s t d fa a t s o v t a sp a tato

M as t a sam as s a d S p od ca y pat s c v g o g t m t apy wt d c of ac b ca s s v pato ox c ty may d v op wt o t a p od om of d st g s g symp oms opt m m t m s o ma g t fi st a d s bs q t t a sam as m as m s a ot ow as d o c ca t a data a d postma t g xp c s t a sam as s s o d b mo to d wt o 8 w s aft t at g t atm t wt d c of ac

ow v s v pat c act o s ca occ at a y t m d g t atm t wt d c of ac If ab o ma v t sts p s st o wo s f c ca s g s a d/o symptoms co s st t wt v d s as d v op o f syst m c ma f stat o s occ g os op a as abdom a pa d a a da c d sco t c of ac otass m fo a So to mm d at y

o m m z t poss b ty t at pat c y w b com s v b tw t a sam as m as m ts o m pat ts of t wa g s g s a d symptoms of pa otox c ty g a s a fat g t a gy d a a p t s a d c g t pp q ad a t t d ss a d fl symptoms a d t app op at act o pat ts s o d ta f t s g s a d symptoms app a

o m m z t pot ta s fo a adv s v at d v t pat ts t at d wt c of ac otass m fo a So to s t ow st f ct v dos fo t s o t st d ato poss b x c s ca to w p sc b g c of ac otass m fo a So to wt co com ta t d gs t at a ow to b pot ta y patotox c g ac tam op c a a t bot cs a t p ptc s a to pat ts to avo d ta g o p sc pto ac tam op co a g p od cts w s g c of ac otass m fo a So to

5.4 Hypertension

NS I s c d g c of ac otass m fo a So to ca ad o w o s t o wo s g of p x st g yp t so t of w c may co t b t o t c as d c d c of V v s Us NS I s c d g c of ac otass m fo a So to wt ca to pat s wt yp t so Mo to b ood p ss c os y d g t tato of NS I t atm t a d t o g o t t co s of t apy

at ts ta g b o s t azd s o oop d t cs may av mpa d spo s to t s t ap s w ta g NS I s

5.5 Congestive Heart Fa lure and Edema

d t to a d d ma av b obs v d som pat ts ta g NS I s Us c of ac o ass m fo a So to wt ca to pat s wt fl d t to o a t fa

5.6 Renal Effects

Us ca to w tat g t atm t wt c of ac otass m fo a So to pat ts wt co s d ab d yd ato

o g t m adm st ato of NS I s as s t d a pap a y c oss a d ot a y a tox c ty as a so b s pat ts w om a p ostag a d s av a comp sato y o t ma t a c of a p f so I t s pat s adm st ato of a NS I may ca s a dos d p d t d cto p ostag a d fo mato a d s co da y a b ood flow w c may p c p at ov t a d comp sato at s at g at st s of t s acto a t os wt mpa d a f cto a t fa v dysf cto t os ta g d t cs o b to s a d t d y sco t ato of NS I t apy s s a y fo ow d by cov y to t p t atm t stat

No o mat o s ava ab f om co t o d c ca st d s ga d g t s of c of ac otass m fo a So to pat ts wt adva c d a d s as fo t atm t wt c of ac o ass m fo a So to s ot comm d d pat ts wt adva c d a d s as If c of ac o ass m fo a So to t apy m st b tat d c os mo to g of t pat ts a f cto s adv sab

5.7 Anaphylac oid Reactions

s wt ot NS I s a ap y acto d act o s may occ pat ts wt o t ow p o xpos to c of ac o ass m o a So to c of ac o ass m o a So to s co t a d cat d pat s wt t asp t ad s symptom comp x typ ca y occ s ast mat c pat ts w o xp c ts wt o wt o t asa po yps o w o x b t s v pot t a y fata b o c ospasm a t ta g asp o ot NS I s *[see* **CON RAINDICA ONS (4)***]*.

5.8 Serious Skin Reactions

NS I s c d g c of ac otass m fo a So to ca ca s s o s adv s act o s s c as xfo at v d mat t s St v s o so Sy d om S S a d tox c p d ma c oyss N w c ca b aa s s o s v ts may occ wt o t wa g I fo m pat ts abo t t s g s a d symp oms of s o s ma f stat o s a d to d sco t c of ac otass m fo a So to at t fi st app a a c of s as o a y ot s g of yp s st v ty

5 9 Pregnancy

c of ac otass m fo a So to ca ca s f a a m w adm st d to a p g a t woma S a t g at 30 w s g s ato c of ac o ass m fo a So to a d ot NS I s s o d b avo d d by p g a t wom as p mat c os of t d ct s a t os s t f t s may occ If t s d g s s d d g t st m p od p g a cy t pat ts o d b app s d of t pot ta aza d to a f t s *[see* **Use in Special Popula ions (8 1)***]*.

5.10 Masking of Inflammation and Fe er

p a maco og ca act v ty of NS I s d c g flammat o a d poss b y f v may d m s t t y of t s d ag ost c s g s d t ct g comp cat o s of p s m d o f cto s pa f co d to s

5.11 Hematological Effects

ma may occ pat ts c v g NS I s s may b d to fl d t to occ t o g oss I b ood oss o a comp t y d sc b d ff ct po yt opo ss I pat ts o o g t m t a y wt NS I s c d g c of ac o ass m fo a So to c c mog ob o matoc t f t y x b t a y s g s o symp oms of a m a o b ood oss

NS I s b t pat t agg gat o a d av b s ow o p o o g b d g t m som pat ts U asp t NS I ff ct o pat t f cto s q a t tat v y ss of s o t d ato a d v sb a f y mo to pat ts t at d wt c of ac otass m fo a So to w o may b adv s y aff ct d y at ato s pat t f cto s c as t os wt coag ato d s o d s o pat s c v g a t coag a ts

5.12 Use in Patients Wi h Preexistent Asthma

at ts wt ast ma may av asp s st v ast ma s of asp pat ts wt asp s st v ast ma as b assoc at d wt s v b o c ospasm w c ca b fata S c c oss act v ty c d g b o c ospasm b tw asp a d ot NS I s as b po t d s c asp s st v pat ts c of ac otass m fo a So to s co t a d cat d pat ts wt t s fo m of asp s st v ty a d s o d b s d wt ca to a pat ts wt p x st g ast ma

5.13 Monitoring

ca s s o s I c ato s a d b d g ca occ wt o t wa g symptoms p ys ca s s o d mo to fo s g s o symp oms of I b d g

o pat ts o o g t m t atm t wt NS I s c d g c of ac o ass m o a So to p od ca y p fo m a a d c m st y p ofi sco t c of ac o ass m fo a So to f ab o ma v t sts o a t sts p ss to wo s

5.14 Pheny ketonurics

c of ac otass m fo a So to co ta s p y a a 22 5 mg p ac 50 mg pac t

6 ADVERSE REAC IONS

fo ow g s o s adv s act o s a d sc ss d s w t ab g

- a d ovasc a t ombot c v ts *[see* **BOXED WARNING** *and* **Warnings and Precautions (5 1)***]*
- ast o t st a ff cts *[see* **BOXED WARN NG** *and* **Warn ngs and Precautions (5 2)***]*
- pat c ff cts *[see* **Warnings and Precautions (5 3)***]*
- yp t so *[see* **Warnings and Precautions (5 4]**
- o g st v a t a a d d ma *[see* **Warn ngs and Precautions (5 5)***]*
- a f cts *[see* **Warnings and Precautions (5 6)***]*
- ap y acto d act o s *[see* **Warn ngs and Precautions (5 7)***]*
- S o s S act o s *[see* **Warnings and Precautions (5 8)***]*

most commo adv s act o s po t d wt c of ac otass m fo a So to a a s a a d dzz ss

most commo adv s v ts s t g d sco t ato of pat ts fo ow g c of ac o ass m fo a So to dos g co to d c ca t as w tca a 0 2% a d fl s g 0 2%

6.1 Clinical Stu ies Experience With Diclofenac Potassium for Oral Solution

ca s c ca t as a co d ct d d wd y va y g co d to s adv s act o at s obs v d t c ca t as of a d gca ot b d ct y compa d wt at s t c ca t as of a ot d g a d may ot fl ct t at s obs v d p act c

saf ty of a s g dos of c of ac otass m o a So to was va at d 2 p ac bo co t o d t a s wt a tota of 63 m g a pat s t at d wt c of ac otass m fo a So to fo a s g m g a adac o ow g t atm t wt d c of ac potass m t c of ac otass m fo a So to o d c of ac po ass m mm d at as tab ts [as a co t o] 5 s b cts 0 8% wt d w f om t st d s fo ow g p ac bo xpos s b ct 0 2% wt d w No wt d awa s w d to a s o s acto

most commo adv s act o s t at occ d % o mo of c of ac o ass m fo a So to t at d pat ts a d mo f q t wt c of ac otass m fo a So to t a wt pac bo w a s a a d dzz ss s **able 1**

Table : Treatment Related Ad erse Reactions With Incidence > % and Greater han Placebo in Stu ies 1 and 2 Combined

Disorder v t	**DICLOFENAC POTASS UM FOR ORAL SOLUTION** N=63	**Placebo** =6 6
Gastrointestinal Na s a	3%	2%
Nervous System zz ss	%	0 5%

6 2 Ad erse Reactions Reported With Diclofenac and Other NSAIDs

I pat ts a g d c of ac o ot NS I s t most f q ty po t d adv s act o s occ g app ox mat y % o 0% of pat ts a I act o s c d g abdom a pa co st pat o d a a dysp ps a flat c g oss b d g/p o ato a tb a s a I c s [gast c/d od a] a d vom t g ab o ma a f cto a m a dzz ss d ma vat d v zym s adac s c as d b d g t m p t s as s a d t ts

dd to a adv s act o s po t d pat ts a g NS I s c d occas o a y

odyasaWo v f cto s pss

adovasc a ystm o g st v a t fa yp t so tac yca d a sy cop

g st v Syst m y mo t sop ag t s gast c/p pt c c s gast t s gast o t st a b d g g oss t s mat m s s patt s a d c

m ca d ym at c yst m cc ymos s os op a op a m a p p a cta b d g stomat t s t omboc yop a

M tabo c a d N t to a W g t c a g s

N vo s yst m x ty ast a co f so d p sso d am ab o ma t s d ows ss som a ma a s vo s ss pa st s a som o c t mo s v tgo

s ato y yst m st ma dysp a

a d ag s op ca p otos s t v ty s w at g c as d

Sp ca S s s d v so

U og ta Syst m yst t s dys a mat a t st t a p t s o g a/po y a p ot a a fa

t adv s act o s pat ts ta g NS I s w c occ a y a

odyasaWo ap y act c act o s app t t c a g s d at

a d o asc a yst m yt m a ypot so myoca d a fa cto pa p tat o s vasc ts

g st v yst m o t s c ato v fa pa c atts

m c a d ymp at c Syst m g a ocy os s mo yt c a m a apast c a m a ymp ad opat y pa cytop a

M tabo c a d N t to a yp g yc m a

o s yst m o v so s coma a c ato s m g t s

sp ato y Syst m sp ato y d p sso p mo a

S a d pp dag s go d ma tox c p d ma c oyss yt ma m t fo m xo at v d matts St v s o so sy d om t ca a

Sp ca S s s o ct v t s a g mpa m t

7 DRUG IN ER CTIONS

7.1 Aspirin

W adm st d wt asp d c of ac potass m s pot b d g s d c d c ca s g fica c of t s t acto s ot ow ow v as wt ot NS I s co com ta t adm st ato of c of ac otass m fo a So to a d asp s ot g a y comm d d b ca s of t pot ta of c as d adv s ff c s

7 2 Anticoagulants

f cts of a t coag a ts s c as wa a a d NS I s o I b d g a sy g st c s c t at s s of bot d gs og t av a s of s o s I b d g g t a t at wt s of t d g a o

7 3 CE Inh bitors

NS I s may d m s t a t yp t s v ff ct of b to s s t acto s o d b g v co s d ato pat ts ta g c of ac otass m o a So to co com ta t y wt b o s

7 4 Diuretics

ca st d s as w as post ma t g obs vat o s av s ow t at d c of ac potass m ca d c t at t c ff ct of f os m d a d t azd s som pat ts s spo s as b att b t d o b to of a p ostag a d syt ss g co com ta t t apy wt NS I s obs v pat ts co s y fo s g s of a fa as w as to ass d t c ficacy *[see* **Warnings and Precautions (5 6)***]*

7 5 Lithium

NS I s av p od c d vat o s of p asma t m v s a d a d cto a t m c a a c m a m m m t m co c tato c as d 5% a d t a c a a c was d c as d y app ox mat y 20% s f cts av b att b t d to b to of a p ostag a d syt ss by t NS I W c of ac otass m fo a So to a d t m a adm st d co c ty obs v pat ts ca f y fo s g s of t m tox c ty

7.6 Methotrexate

NS I s av b pot d ocomp ttv y btm t ot xat acc m ato abbt d y s c s s dcat s t at NS I s may a c t toxcty of m t ot xat Us ca to w NS I s a adm st d co com a ty w t m t ot xat

7.7 Cyclosporine

cof ac o ass m fo a So to ot NS I s may aff ct a pos ag a d s a d c as t oxcty of c ta d gs o co com ta t t apy w t cof ac otass m fo a So to may c as cyc ospo s p o oxcty Us ca to w cof ac otass m fo a So to s adm st d co com a ty w t cyc ospo

7.8 Inhibitors of Cytochrome P450 2C9

cof ac o ass m fo a So to ot s d a d dom a ty by yoc om 50 Y 2 9 o adm st ato of m dcato s t at bt Y 2 9 may aff ct p a maco t cs of d cof ac *[see* **Cl nical Pharmacology (12 3)**].

8 USE IN SPECIFIC POPULA IONS

8.1 Pregnancy

Pregnancy Category C prior to 30 weeks gestation; Category D starting at 30 weeks gestation.

Sta t g at 30 w s g stato cof ac otass m fo a So to a d ot NS I S s o d b avo d d yp g a t wom as p mat cos of t d ct s at os s t f t s may occ *[see* **Warn ngs and Precautions (5 9)**]. a oad q at a dw co to d st d s p g a t wom

o to 30 w s g sato cof ac otass m fo a So to s o d b s d d gp g a cy o y f t pot t a b ft st fi st pot t a s tot f t s

p od ctv st d s av b p o m d mc gv d cof ac sod m p to 20 mg/ g/day 2 t m s t comm d d ma dos [ ] of 50 mg/day o a body s fac a a [mg/m² bas s a d ats a d abb s gv d cof ac sod m p to 0 mg/ g/day 2 [ats] a d [abb ts] t m s t o a mg/m² bas s a d av v a d o vd c of t aog ctyd spt t d cto of mat a toxcty a d f ta oxcty t ats mat a y oxc dos s w assoc at d wt dystoc a p oo g d g stato d c d f ta w g ts a d g owt a d d c d f ta s vva

8.2 Labor and Delivery

ff c s of cof ac o ass m fo a So to o abo a d d v y p g a t wom a ow I at st d s mat a xpos to NS I s as wt ot d gs ow to bt p ostag a d sy t ss c as dt cd c of dystoc a d ay d pat to a d d c as d p ps vva

8.3 Nursing Mothers

It s ot ow w t t s d g s xc t d ma m ca s ma y d gsa xc t d ma m a d b ca s oft pot t a fo s o sadv s actos s g fa ts fom cof ac o ass m fo a So to a d cso s o d b mad w t to dsco t s g o to dsco t t d g ta g to acco t t mpo ta c of t d g to t mot

8.4 Pediatric Use

Saf ty a d ff ctv ss p d at c pat ts av ot b stab s d

8.5 Geriatric Use

ca st d s of cof ac o ass m fo a So to dd ot c d s ffic t mb s of s b csag d 65 a d ov od t m w t t y spo d d ff ty f om yo g s b cts

d y pat s a at c as d s fo s os ladv s v ts

cof ac s ow to b s bsta ta y xc t d by t d y a d t s of adv s actos ot s d g may b g at pat ts wt mpa d a f cto ca s d y pat sa mo yo av d c as d a f cto ca s o d b a w s g cof ac otass m fo a So to t d y

8.6 Hepatic Impairment

ca s pat c m tabo sm acco ts fo a most 00% of d c of ac m ato pat ts wt pat c mpa m t s o d b co sd d o t atm twt cof ac otass m o a So to o y f t b fi so tw g t s s s s ffic t o mato ava ab o s ppo t dos g comm dato s fo cof ac otass m o a So to pat ts wt pat c s fic cy *[see* **Clinical Pharmacology (12 3)**].

8.7 Renal Impairment

No fo mato s ava ab f om co to d c ca st d s ga d g t s of cof ac o ass m o a So to pat s wt adva c d a ds as fo t atm t wt cof ac otass m fo a So to s ot comm d d pat ts wt adva c d a ds as If cof ac otass m fo a So to t apy m st b tat d c os mo o g of t pat ts a f cto s adv sab

0 OVERDOSAGE

ymptoms o ow g a c t NS I ov dos s a s ay mt d o t a gy d ows ss a s a vomt g a d pgast c pa w c a g ay v sb wt s ppo tv ca asto t st a b d g ca occ yp t so act a fa sp ato y d p sso a d coma may occ b t a ap yactod actos s av b pot d wt t ap tc g sto of NS I s a d may occ fo ow g a ov dos

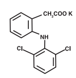
at ts s o d b ma ag d by symp omat c a d s ppo tv ca fo ow g a NS I ov dos a o sp cfic a tdot s m ss a d o actvat d c a coa 60 to 00 g a d s to 2 g/ g c d a d/o osmotc cat a t c may b dcat d pat ts s wt o s of g sto wt symptoms o fo ow g a a g ov dos 5 to 0 t m s t s a dos o c dd ss a a zato of mod a yss o mop f so may ot b s f d o g pot b d g

11 DESCR PT ON

cof ac otass m fo a So to s a b z ac tc acd d vatv NS I cof ac otass m fo a So to s ava ab as a flavo d so b powd d sg d tob mx dwt wat p o o o a adm st ato

cof ac otass m fo a So to s saw t too f w t flavo d powd o o a so to pac ag d dvd a t dos pac ts *[see* **HOW SUPPL ED/S ORAGE AND HANDLING (16)**].

c m ca am fo d cof ac potass m s 2 [2 6 dc o op y am o] b z ac tc acd mo opotass m sat mo c a w g t of d cof ac po ass m s 33 25 Its mo c a o m as $_2$NK $_2$ a d t as t o ow g st ct a fo m a



actv g d ts cof ac otass m fo a So to c d spa tam q va t to 22 5 mg p y aa p pp m t flavo gyc y b at ma o po ac a potass m a d sacc a sod m

2 CLIN CAL PHARMACOLOGY

2.1 Mechanism of Action

cof ac otass m o a So to sa o st o da a t flammato y d g NS I m c a sm of acto of cof ac o ass m fo a So to t at of ot NS I s s ot comp t y d stood b t may b at d o p ostag a d sy t tas b to

2 3 Pharmacokine ics

bso pto cof ac s 00% abso b d aft o a adm stato compa d to t av o s adm stato as m as d y cov y ow v d to fi st pass m tabo sm o y abo t 50% of t abso b d dos s syst mca y ava ab l fast g vo t s m as ab pasma v s w obs v d wt 5 m t of dos g wt cof ac otass m o a So to a pasma v s w ac v d at app ox mat y 0 25 o fast g o ma vo t s wt a a g of 0 to 06 o s g fat food ad o sg fica t ff ct o t xt t of d cof ac abso pto b t t was a d cto p a pasma v s of app ox mat y 0% aft a g fat m a c as d $_{max}$ may b assoc at d d o c as d ff ctv ss

st b to appa t vo m of d st b to V/ of d cof ac potass m s 3 / g

cof ac s mo t a 99% bo d to ma s m pot s p ma y to alb m S m pot b d g s co sta t ov t c oc t ato a g 0 5 to 05 mcg/m ac v d wt comm d d dos s

ta o sm v d cof ac m abo ts av b d tfi d ma pasma a d m abo t s c d yd oxy 5 yd oxy 3 yd oxy 5 d yd oxy a d 3 yd oxy m t oxy d cof ac mao d cof ac m tabo t yd oxyd cof ac as v yw a p a macoog c actvty fo mato of yd oxy d cof ac s p ma y m dat d by Y2 9 ot d cof ac a d ts oxdatv m tabo t s d gog c o dato o s fato o ow d by b ay xc to cyg c o dato m dat d by U 2 a d ox dato m dat d by Y2 8 may aso pay a o d cof ac m abo sm Y 3 s spo sb fo t fo mato of m o m tabo t s 5 yd oxy a d 3 yd oxy d cof ac I pat ts wt a mpa m t p a coc t ato s of m abo t s yd oxy a d 5 yd oxyd cof ac w app ox mat y 50% a d % of t pa t compo d at s g o a dos g compa d o 2 % a d % o ma at y s b cs

xc to cof ac s m at d t o g m tabo sm a d s bs q t a y a d b ay xc to of t g c o d a d t s fat co gat s of t m abo t s t o f ca g d d cof ac s xc t d t pp ox mat y 65% of t dos s xc t d t a d app ox mat y 35% t b as co gat s of ca g d d cof ac p sm tabo t s ca s a m ato s ot as g fica t pat way of m ato o ca g d d cof ac dos g ad stm t pat ts wt m d to mod at a dysf cto s ot c ssa y t m a af f of ca g d d cof ac s app ox mat y 2 o s

ca o at o s

Race: a o p a maco t c d ff c s d to ac

Hepatic Impairment: v m abo z s a most 00% of d c of ac t s s ffic t o mato ava ab o s ppo t dos g comm dato s fo cof ac o ass m fo a So to pat ts wt pat c s fic cy 5 3 8 6

Renal Impairment: I pat ts wt a mpa m t c a a c 60 to 90 30 to 60 a d 30 m /m N=6 ac g o p U va sa d m ato at w compa ab to t os at y s b c s

3 NON CLIN CAL STUDIES

3.1 Carcinogenesis, Mutagenesis, Impairment of Fert lity

o g t m ca c og ct y st d s ats gv d cof ac sod m p to 2 mg/ g/day ss t a t comm d d ma dos [ ] of 50 mg/day o a body s fac a [mg/m²] bas s av v a d o sg fica t c as s t mo c d c was as g t c as b g mamma y fib oad omas m d dos t at d 0 5 mg/ g/ day o 3 mg/m²/day f ma ats g dos f ma s ad xc ssv mo ta y b t t c as was ot sg fica t o t scommo att mo 2 y a ca c og ct y st dy c o d ct d mc mpoy g d cof ac sod m at dos s p to 0 3 mg/ g/day ss t a t o a mg/m² bass ma sa d m/ g/day ss t a t o a mg/m² bass f ma s dd ot v a a yo cog c pot ta

cof ac sod m was ot g otox c *in vitro* v s m ato bact a [m s] mo s ymp oma t o *n vivo* c d g dom a t t a a d ma g m a pt a c omosoma ab ato s amst assays

cof ac sod m adm st d to ma a d f ma as at mg/ g/day ss t a t o a mg/m² bas s dd ot a f ct f t ty

14 CLIN CAL STUDIES

fficacy of cof ac otass m fo a So to t ac t t atm t of m g a adac was d mo st at d two a dom z d do b b d pac bo co to d t as

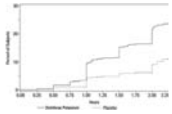
at ts o d t s two t as w p dom a ty f ma 85% a d w t 86% wt a m a ag of 0 y as a g 8 to 65 at sw st ct d tot at m g a of mod at to s v pa wt dos of st dy m dcato at ts va at dt adac pa 2 o s at ssoc at d symp oms of as a s a p otop oba a d p o op oba w aso va at d I add to t p opo to of pat ts w o w s sta d pa f d fi d as a d cto adac s v ty f om mod at o s v pa to o pa at 2 o s post dos w t o ta t of m d mod at o s v pa a d o s of sc m dcato fo 2 o s post dos was as o va at d I t s st d s t pc tag of pat ts ac v g pa f dom 2 o s aft t atm t a s sta d pa f dom f om 2 o 2 o s post dos was s g fica t y g at pat ts w o c v d cof ac otass m o a So to compa d w t t os w o c v d pac bo s **able 2** p c tag of pat ts ac v g pa f 2 o s aft t atm t d fi d as a d cto adac s v ty f om mod at o s v pa to mo do o pa was as o s g fica t y g at pat ts w o c v d cof ac otass m fo a So to compa d w t t os w o c v d pac bo s **able 2**

Table 2: Percentage of Patients With 2 Hour Pain Freedom, Sustained Pain Freedom 2 o 24 Hours, and 2 Hour Pain Relief Fo lowing T eatment

Study 1	Diclofenac Potassium for Oral Solution (n=265)	Placebo (n 257)
2-Hour Pain Free	2 %	13%
2-2 h Sustained Pain Free	22%	10%
2-Hour Pain Relief	8%	27%
Study 2	**Diclofenac Potassium for Oral Solution (n=343)**	**Placebo (n 347)**
2-Hour Pain Free	25%	10%
2-2 h Sustained Pain Free	19%	7%
2-Hour Pain Relief	65%	1%

st mat d p obab ty of ac v g m g a adac pa f dom wt 2 o s fo ow g t atm twt cof ac otass m o a So to s s ow **Figure 1**

Figure 1. Percentage of Patients With Initial Headache Pain Freedom Within 2 Hours



was a d c as d c d c of a s a p otop ob a a d p o op oba fo ow g adm st ato of cof ac otass m fo a So to compa d to pac bo fficacy a d saf ty of cof ac o ass m fo a So to was aff ct d by ag o g d of t pat t

6 HOW SUPPLIED/STORAGE AND HANDLING

cof ac otass m fo a So to 50 mg s s pp d as dvd a dos pac ts ac dvd a pac t s d sg d to d v a dos of 50 mg d cof ac po ass m w mx d wat

cof ac otass m fo a So to s saw t too f w t flavo d powd o o a so to pac ag d dvd a t dos pac ts

I dvd a cof ac otass m o a So to ac t N 988 905 52

ox s of t 3 cof ac otass m fo a So to ac ts N 988 905 2

ox s of 9 cof ac otass m fo a So to ac ts N 988 905 6

Sto at 25 xc sos p mtt d f om 5 to 30 59 to 86 [S US o to d oom mp at].

17 PA IENT COUNSELING INFORMAT ON

I fo m pat ts of t ava ab ty of a M dcato d fo NS I st at accompa s ac p sc pto dsp s d a d st ct t m to adt M dcato d p o to s g cof ac otass m fo a So to *[see* **Medica tion Guide (17 9)**].

17.1 Cardio ascular Effects

cof ac otass m fo a So to ot NS I S may ca s s os V v ts s c as MI o st o w c may s t osp ta zato a d v d at t o g s o s V v s ca occ wt o t wa g symptoms advs pat s o b a t o t sg s a d symptoms of c st pa s ot ss of b at wa ss s g of sp c a d o as fo m dca advc w obs v g a y dcatv sg o symptoms I fo m pat ts of t mpo ta c of t s fo ow p *[see* **Warnings and Precautions (5 1)**].

17 2 Gastrointestinal E fects

cof ac otass m fo a So to ot NS I S ca ca s ld scomfo t a d mo s o s ladv s v ts s c as c s a d b d g w c may s t osp ta zato a d v d at t o g s o s I tact c ato s a d b d g ca occ wt o t wa g symptoms advs pat s o b a t o t sgs a d symptoms of c ato s a d b d g a d to as fo m dca advc w obs v g a y dcatv sg o symptoms c d g p gast c pa dysp ps a m a a d mat m s s I o m pat s of t mpo ta c of t s o ow p *[see* **Warnings and Precautions (5 2)**].

17 3 Hepato o icity

I fo m pat s of t wa g s g s a d symp oms of patotox cty g a s a fatg t a gy p t s a dc gt pp q adat t d ss a d fl symptoms I st ct pat ts to stop t a y wt cof ac otass m fo a So to a ds mm dat m dca t apy fa y of t s occ *[see* **Warnings and Precautions (5 3)**].

17.4 Weight Gain and Edema

dvs pat ts to p ompty po t to t p ysca s s g s o symp oms of xpa d w g t ga o d ma d gt atm twt cof ac o ass m fo a So to *[see* **Warnings and Precautions (5 5)**].

17.5 Anaphylactoid Reactions

I fo m pat s of t sg s of a a p yactod acto g d fic ty b at g sw g of t ac o t oat I st ct pat s to s mm dat m g cy p f t s occ *[see* **Warnings and Precautions (5 7)**].

17.6 Adverse Skin Reactions

cof ac o ass m o a So to ot NS I S ca ca s s o ss acto s s c as xfo atv d matts St v s o so sy dom S S a d toxc pd ma c oss N w c may s t osp ta zato s a d v d at t o g s o ss acto s may occ wt o t wa g adv s pat ts to b a t fo t sg s a d symptoms of s as a d b st s f v o ot sg s of yp s s tv ty s c as tc g a d to as o m dca advc w obs v g a y dcatv sg s o symp oms dvs pat ts to stop cof ac otass m fo a So to mm dat y ft y d v op a y typ of as a d to co act t p ysca s as soo as poss b *[see* **Warnings and Precautions (5 8)**].

17.7 E fects During Pregnancy

Sta t g at 30 w s g stato cof ac otass m fo a So to a d ot NS I s s o d avo d d by p g a t wom as p mat cos of t d ct s at os s t f t s may occ *[see* **Use in Specific Popu ations (8 1)**]

17.8 Pheny ketonurics

cof ac otass m fo a So to co ta s y aa 22 5 mg p ac 50 mg pac t

17.9 FDA Approved Medication Guide

Upo dsp s g to a pat t p as s t pat t c v st attac d M dcato d

MEDICAT ON GUIDE
DICLOFENAC POTASSIUM for oral solution
dye KLOE fen ak poe-TAS ee um

ad t at tl o mato t at com s wt cof ac otass m o a So to b fo yo sta t a g t a d ac tm yo g ta fi may b w fo mato s aft t do s otta t pac of ta g wt yo doc o abo tyo m dca co dto o yo t atm t

What is the most mportant information I should know about Diclofenac Potassium for Oral So ution?

Diclofenac Potassium for Oral So ution, which contains dic ofenac, (a non-steroidal anti-inflammatory drug or NSAID) may increase your chance of a heart attack or stroke that can lead to death his chance is higher:

- w t o g s of NS I m dc s
- p op w o av a t ds as

NSA D medicines such as Diclofenac Potassium for Oral Solution shou d never be used right before or after a heart surgery ca led a "coronary ar ery bypass graft" CABG)

NSA D medic nes such as Diclo enac Potassium for Oral Solu ion can cause ulcers and bleeding in your stomach and intestines at any time during treatment

Ulcers and b eeding:

- ca app wt o t wa g symptoms
- may ca s d at

he chance of a person gett ng an u cer or bleeding increases w th:

- t s of m dc s ca d st od o mo s co tcost o ds a d b ood t s a t coag a ts
- o g o g a s
- smo g
- d g a co o
- o d ag
- av g poo at

Diclofenac Potass um for Oral Solution should only be used:

- xacty as p sc b d
- at t ow st dos poss b fo yo t atm t
- fo t s ot st t m d d

What is Diclofenac Potass um for Oral Solution?

cof ac otass m fo a So to s a p sc pto m dc s d tot at m g a a tac s ad ts It do s ot p v to s t mb of m g a s yo av a d t s ot fo ot typ s of adac s cof ac otass m fo a So to co ta s d cof ac po ass m a No St o da t I flammato y g o NS I

How shou d I take Diclofenac Potassium for Oral Solu ion?

a cof ac o ass m fo a So to xacty as yo at ca povd t s yo to a t

a dos of cof ac otass m fo a So to tot at yo m g a adac

- mov o s g dos pac t f om as t of t pac ts
- op pac to y w yo a ady to s t
- mpty co t s of pac t to to 2 o c s 2 o ab spoo s of wat
- mx w a d d t wat a d powd m xt
- t ow away mpty pac t a saf pac a d o t of t ac of c d
- ta g cof ac otass m o a So to wt ood may ca s a d cto ff ctv ss compa d to ta g cof ac otass m o a So to o a mpty stomac
- do ot ta mo cof ac otass m o a So to t a d ct d by yo at ca povd I cas of ov dos g t m dca p o co tact a oso o to t g t away

Who shou d not ake Diclofenac Potassium for Oral So ution?

o ot ta cof ac otass m fo a So to

- g t b fo o aft a t bypass s g y S W at s t most mpo ta t o mato I s o d ow abo t cof ac otass m o a So to
- f yo av o av ada ast ma attac v s o ot a g c acto wt asp d cof ac o a yot NS I m dc

Before you ake Diclofenac Potassium for Oral Solution tell your healthcare provider about a yo m dca co dto s c d g f yo

- av a s o y of stomac c o b d g yo stomac o t st s
- av d yo v p ob ms
- av a y a g s o a y m dc s
- av c st pa s ot ss of b at g a a tb as
- a p g a t t yo mg t b p g a t o a ty g to b com p g a t cof ac o ass m fo a So to s o d ot b s d by p g a t wom sp ca y d gt ast 3 mo t s of p g a cy ss d ct d by yo at ca povd to do so cof ac otass m o a So to may ca s p ob ms yo bo c do comp cato s d g yo d v y
- a b astf d g o pa to b as f d It s ot ow f cof ac otass m pass s to yo b ast m Yo a d yo doc o s o dd cd f yo w ta cof ac otass m fo a So to o b astf d Yo s o d ot do bot
- av a adac t at s d f t f om yo s a m g a

ell your doctor about all the med c nes you take c d g p sc pto a d o p sc pto m dc s vta m s a d ba s pp m ts

cof ac otass m o a So to a d ot m dc s may aff ct ac ot ca s g sd ff cts cof ac otass m fo a So to may aff ct way ot m dc s wo a d ot m dc s may aff ct ow cof ac otass m o a So to wo s

Espec ally ell your doctor if you take:

- asp
- a y a t coag a tm dc s wa fa o mad a tov

K owt m dc s yo a K pa st of yo m dc s a d s ow t to yo docto a d p a macst w yo g ta w m dc

What are the poss ble side effects of Diclofenac Potassium for Oral Solution?

Serious side effects include:

- a tat ac
- st o
- g b ood p ss
- at fa f om body sw g fl d t to
- d y p ob ms c d g d y fa
- b d g a d c s t stomac a d t st
- ow d b ood c s a ma
- f t at g s actos
- f t at ga gc acto s
- v p ob ms c d g f t at g v fa
- ast ma a tac s p op w o av ast ma

Get emergency he p r ght away if you have any of the following symptoms of heart attack or stroke:

- s o t ss of b at o to b b at g
- c st pa
- sw g of yo ac o t oat
- w a ss o pa to o sd of yo body
- s d sp c

Common s de e fects include:

- a s a
- dzz ss

Stop Diclofenac Potassium for Oral Solution and call your healthcare provider right away if you have any of the following symptoms:

- a s a t ats ms o t of p o p to o yo m g a
- stomac pa
- s dd o s v pa yo b y
- vom t b ood
- b ood yo bow mov m to t s b ac a d st c y ta
- tc g
- s as o b st s wt f v
- y ows o y s
- sw g of yo a ms a d gs a ds a d f t
- s a w g t ga
- mo t do w a ta s a
- fl symptoms

yo at ca povd f yo av a y s d f cts t at bot yo o do ot go away

s a ota t s d f cts wt NS I m dc s s a to yo at ca povd o p a macst fo mo fo mat o abo t NS I m dc s

a yo at ca povd fo m dca advc abo t s d ff cs Yo may po t s d ff cts o at 800 088

How shou d I store Diclo enac Potass um for Oral Solution?

- sto cof ac o ass m fo a So to a d y p ac at oom t mp at b tw 59 to 86 5 to 30
- p cof ac o ass m fo a So to a d a m dc so t of ac of c d

General nformation about Diclofenac Potassium for Oral So ution

- m dc s a som tm s p sc b d fo p pos s ot t a t os st d a M dcato d o ot s cof ac otass m o a So to fo a co dt o o w c t was ot p sc b d
- do ot gv cof ac otass m fo a So to oot p op v f t y av t sam p ob m yo av It may a m t m
- t s M dcato d co ta s t most mpo ta t fo mato abo t cof ac otass m fo a So to If yo wo d mo fo mato ta wt yo at ca povd Yo ca as yo at ca povd fo fo mato w t fo at ca p of sso as
- fo mo fo mato ca a amac t ca l c at 800 28 9393

What are the ingredients in Diclofenac Po ass um for Oral So ution?

Active ngred ents: cof ac po ass m

Inactive ingred ents: spa am q va t to 22 5 mg p yaa p pp m t flavo gyc y b at ma to po ac a po ass m a d sacc a sod m

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his Medication Guide has been approved by the U S Food and Drug Administration