PACKAGE LEAFLET: INFORMATION FOR THE USER Denakine® 200 mg/ml oral solution

his medicine is subject to additional monitoring. This will allow quick identification of new salety information. You can help by urling any side effects you may get. See the end of section 4 for how to report side effects.

WARNING DEPAKINE CAN SERIOUSLY HARM AN UNBORN CHILD WHEN TAKEN DURING PREGNANCY.

Children exposed to valgroute in utero thave a high risk of services developmental disorders; intellectual and motor) and behavioural disordranges (up to 30 to 40% of cases) and/or high defects (approximately 11% of cases). If you are a female child, a female adolescent, a woman or childrening age: your specialist dictor will only prescribe valgroute for you if other treatments are not effective or not tolerated;

of no other treatment is possible, valoroate will be prescribed for you and dispensed under the very strict conditions of a pregnancy prevention program, which aims to prevent any potential pregnancy.

If valpropile has been prescribed for you and you are a woman of childheaving age, you must, in particular:

- use at least 1 effective method of contraception without interruptions during your entire treatment with Depakine. Your
dector will discuss this with you, but you must also follow the advice in exclosin 2 of this health. * schedule au rugent appointment with your special following readoute in section 2 of this keallet.

* schedule au rugent appointment with your specialist doctor if you want to become pregnant or if you think you are pregnant do not stop taking Depakine unless your doctor has told you; this may worsen your condition.

Make sure that you have read and understood the Patient Guide and signed the Annual Risk Acknowledgement Form given

If you are a man able to father children and valoroate has been prescribed for you, please refer to the paragraph below.

ricenary, seess-resing and return—important information for displexents and men of childrening potential ; lead all of this leaflet carefully before you start taking this medicine because it contains important information for you. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the

same as yours. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4. What is in this leaflet

1 WHAT DEPARTME IS AND WHAT IT IS LISED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DEPAKINE

- nless no other epileosy treatment works for you (see below "Pregnancy, breast-feeding and fertility Important
- Will care or requires.

 19 We have required to the project before the self-to project before Tregueze, becast beening and telum impurumment for the mining and the project of the mining and the project of the project of the mining and the project of the project profession and the project proj
- If you did a memore of your family nake even had service have dieneele, pundicialary resident to see of an "you have ben't, probability probability and probability of the probability

Warnings and precautions

tis medicine can, in very rare cases, cause liver damage (hepatitis) or pancreas damage (pancreatitis), which can be serious and 6-threatering scribe blood tests to regularly monitor your fiver function, particularly during the first 6 months of treatment rimmediately if any of the following signs appear:

"sudden latings, loss of appellic echangion, drossness, swelling of the legs, general malaise, reposted vioriting, nauces, stonach or bowel pan, yellow colour of the skin or eyes (paundice), returned eel pelegic schartes even though you are taking your treatment of colours, yellow colours, and the state of the state of the state of the sking your treatment conveols, even and difficulty breathing.

The risk of liver damage is increased if Depakine is given to children under 3 years of age, people taking other antiepileptic medicinal products at the same hime, or secole with another neurological or metabolic disorder and severe forms of ecolesis.

If, during the atment with Depakine, you or your child experience(§ problems with balance and coordination, feeling of lethangs or docuseed alerties so vomiting, feel your doctor immediately. This may be due to an increased amount of ammonium in the bloce Table to your doctor before tabling this medicine

- in you have sourcy usease pertain latiners. If you have systymic lupus erythematosus (gare disease). If you know or if your doctor suspects that there is a genetic problem caused by a mitochondrial disease in your family, due to a risk of

- sanofi
- I locations of a four destination seed with the real speeds proteins caused by a antichedurid doncer may train this, the to be tell was compared to the contract of contra

re necessary no surprocament. Ir doctor if your child is taking another articolectic beatment or has another neurological or metabolic disease or severe forms of epileosc.

Other medicines and Depaline.

Some medicines rough risk effects of signature and in exercises. Assume constances on a procession of the effects of signature and in exercises. Some medicines rough risk effects of the effects of the

* [Drifts] paragraming immous area or not without any and a strength of the fill pare douth of your tabling:

- actualisms' containing meritories (mexicines goed to lower expensare or cirbon dioxide levels in the blood):

- arbitrary immous containing atternative medical products (medicanes containing atternative) in the arbitrary immous medicanes (medicanes containing atternative) in the arbitrary in the arbit

uter anticipation in colonia procusio increasioni subtannia diamanazzanic, recisiante, priesvisioni, systemiyam, priminore, debendabilard, inflamina, bugarnateke or assissioni, bugarnateke predigine inedigine used so prevent complications that can ocur after bleeding in the brain), especial spacialistic including some drift for food by play. especial spacialistic incediaries, especialistic including some drift food by play in a superiori some desirability in a superiori spacialistic including some discovered some discove

disudire-containing memores incurums uson or mond disorders); edicines containing intimum (medicines used to treat mood disorders); edicines containing metamisale (medicines used to treat pain and fever); methotomate (used to treat cancer and inflammatory diseases);

abstract leded to trust corec and nonmoning foculars forduras great another level for the great property of the property another level for the great property are main-fethers containing postate [to enamyle prompcilin, add-not diprosil], seekinalis, in differen under 3 years of a day, you must anid pring mediones containing salesylates [md-oll your doctor or phrasmatid you are kinnel, have recently taken or might take any other mediones.

Depakine with food, drink and alcohol

Pregnancy, breast-feeding and fertility

Presence of the control of the contr d with taking valproate during pregnancy.

ou must not take Depakine: If you are pregnant, unless no other epilepsy treatment works for you. If you are a woman of childbearing age, unless no other epilepsy treatment works for you and you are able to follow all the steps of

Pick erioted to tolice subprooted during mensurary.

The subsequence of the subsequence o

ien by pergand interes, signating can case creates that decide and may see a humbal cliffed on the evologiment indirectary.

In the based of the signature of the contractive price fields and the contractive of the contractive price fields and the contractive price field and the contractive price field and the contractive price field and the contractive price price

or multimations may allest vision.

"In volute shappine draining architecture of the properties of the

with early childhood development. Uniform affected may be sower to walk and/or fail, and/or have a lower lift than o children, and/or have deficionly with language and/or nempore.

**Authorities operturn disonders are more office diagnosed in children exposed to valgrorate during pregnancy.

**There is evidence that children exposed to valgrorate during pregnancy have an increased risk of developing attention deficiol/specarchivity disonder (ADRIO).

Before prescribing this medicine to you, your specialist doctor will have explained the risks for your haby if you become pregnant while taking valgorable. If you want to become pregnant thereafter, you must not step takine your medication or your methad at "Archedide on a "Arched

while faking valignante. If you want to become programs thereafter, you must not kept taking valignante. If you want to become programs thereafter, you must not kept taking your medication or your method of uniformative programs of the pr

isaproade experiences her first monthly period. Some birth control pills (pestrogen-containing birth control pills) may lower valproade levels in your blood. Make sure you talk to your doctor about the method of contracemon that is the most appropriate for you Please choose the situation that applies to your case in the list below and read the corresponding paragraph:

• An PERSONN AND I AN TAKING DEPROYET.
And STREAM TEACHING THE DEPROYET WITH DEPROYET.
If this is the first time yet have been persorbed Depaine, your specially ductor must explain to you the risks of the treatment for the bound middle five become preparal. If you are of childhearing age, you must use at least 1 effective method of contraception without interruption throughout your breatment with Depainer. Said to your doctor, generologies of ramby platning clinic of you

mend above on concerpoint.

"Getter a fairly contract, our destre will have in that on brashers of the flast subjective works for you." Getter a fairly contract, our destre will have in that on brashers of the flast subject to enable of these reports in each contract of the contract of

oney and can refer you to a specialist for advice on contraception.

outly get regular (all least once per year) appointments with a specialist doctor experienced in the treatment of epilepsy. During specialist, you offect will make a variety ou are aware of the risks and that you have understood the information related to the this constitution, your opcor with mans zone to use a some to a man to this discussion which we have been supposed to the constitution of the cons

might be pregiont.

And MARING FORMANE AND MOT PLANNING TO HAVE A BABY

If you are continuing breatment with Depakine but you are not planning to have a baby, make sure you are using at least 1 effective method of contraception without interruption during your entire treatment with Depakine. Talk to your ductor, generology of contral planning court of your addition controlled producing the controlled planning court of your addition controlled producing to a formal planning court of your death of your ductor.

genaecologist or Tamity painting current you need account of the messages.

Now specialist doctor should check regularly falleast once per year) whether any treatment other than valposate works for you specialist doctor should check regularly falleast once per year) whether any treatment other than valposate works for you Two greates doors award cock regularly in lead one per perigh whether an inclument offer than adjungles work for you. Who shall are all self-left-the-method of contrasping indeed any antitastive coince are a conscapping medium of a definition method had not followed by contrasping in all or doubt duming our ordine that method with the self-left contrasping in a decident duming period the self-left contrasping in the contrasping of the self-left contrasping in the self-left c

is consolidation, your decider will make suffery our common to many and an advantage of the consolidation of the c

AM TAKING DEPAKINE AND PLANNING TO HAVE A BABY

craning and repairming to make a data.

In others who have been on valented are at senious risk of birth defects and problems with development which can be airig. If you are planning to have a baby, first schedule an appointment with your specialist doctor experienced.

carook) deciditing. If you are planning to have a balay, rists (Accessed the appearance man your specimen waves opportunities). Do not stop taking Depainer or your contemption until you have discussed the win your doctor. Your doctor will advise you further and refer you to special door opponeed on the formation of explicits, you foul alternative treatment options can be evaluated early on. Myst specialist can put execut adultion in place so that your pregnancy goes as smoothly as possible and any risks to you and your unborn Add to resoluted at the state of the control of the contr

The related is during to exposite.

The related is during to exposite the state of the related with exposite the state of the related with exposite the state of the related with Department with Department with Department or the related to the rel

including this Cost to the programs, sower they by the pre-entry.

The programs of the progra

might be registed.

ALM PREMANTA AND AM TRAING GEPAINE

Bairs born to replies who have been on uplignate are all serious, right of birth delets, and problems with implicatual and motor
orderspered and observant deleters's which can be sensorly delethrating. Do not stop balance Depause series user decide has build
thin may source; your condition. Schedule as argest appointment with your specialist decider experienced in the treatment of
equiposity on our perspact or think you might be pregnant.

he/Site will advise you further; he/Site should by everything possible to stop the treatment and assess all the other options for treatment. the exestional corporations's when Depalatie is the only available treatment option during preparator; bour doubt many reter you to a specialist so that you and your partner receive counselling and support regarding the valproate-exposed

was assume and TCMT WILL a specialist to that you and your pattern receive controlling and support agenting the vulgrante expound registrate.

For special cloth cloth will be just devices the rescribed doc.

For special cloth controlling and support agent pattern and the production of the support and the pattern and the production of the support and the pattern an

argent appointment with your specialist doctor experienced in the treatment of epilepsy if you are pregnant or think you

Solved a flag disputament was long-posses source operation in residence of epicy if you are popular or may so per Don't dop falling policyparise unless your operated both or person of the operation of the policy to solve of the operation of the policy to solve of the operation of the policy to solve of the operation of the ope

Instituting of the Citia's reasong call development.

Important information for adolescents and men of childhearing notential.

mentating the first first energied an executive.

The design of the sould be compaged an executive of the sould be considered and sould be sould be consider

on, extunence or your symptoms.

Thus must consoll have depended puring this consolution, your door will doors with you the precautions associated with the use of standards and precautions associated with the use of standards and you consolution of other texturements for your decode, expending on your demindual statution. Read the spatiest good grown to you by your decode. A patient card with above beginning to your dynamics to remind you of the protection and you dispose.

Breast-feeding

ast-feed during treatment with this medicine unless otherwise indicated by your doctor. harmacist for advice before taking any medicine.

Driving and using machines
Depalme may cause downess, especially if taken in combination with other anticonsulsants or medicines that can increase drowsiness
If you experience this effect and if your condition is not under control yet and you continue to have escuere, you must not drive or

Depakine 200 mg/ml oral solution contains sodium

3. HOW TO TAKE DEPAKINE Instructions for proper use

Institution for pages as:

(In all external dishipment partial for a second dishipment partial framework places which be started and suprised by a factor specially as the research of coping. This research must not include the pages of the started and suprised by the started page of the dishipment page of the dishipment of the started and under the ordinary pages of the started and under the st

does mill be decided on for you and checked by your doctor.

This information is important because the arings used to draw

is generally unided into. er day in children under 1 year of age. er day in adults and children over 1 year of age.

1085 pc; usay as seed of odes should poelerably be taken during meals. osc remain with the dose crescribed by your doctor. Check with your doctor or pharmacist if you are not sure. Patients with kidney disorders
Vour doctor may decide to adjust your dose.



The oral solution should be taken after diluting in a small amount of son cohemisted from.

The both of our darks on separate with a songing for and administration level integer which is specific with a songing for and administration level integer which is so fair one with this modelline. Thosping for and administration may be an administration may be an administration may be an administration may be an administration may be administration and beautiful as with a modelline from the administration of the administratio

"DEPAINE 200 mg/ml and solution".

Only administr the enal solution with the syringe for oral administration supplied in this box.

The graduation marks indicate doses in milligrams [mg].





Using the springe for and administration

The dose to be administered is obtained by drawing the plunger up to the graduation line corresponding

1) Fill the oringe for oral

into a glass and dilute it in a



After use close the hottle rinse the suringe for oral admin fhen immediately place the syringe for oral administration in its box somewhere out of the reach of children. Never separate the syringe for oral administration from the other elements of the medicine's packaging (box, package leaflet).

Duration of treatment Do not stop taking this medicine without your doctor's advice.

If you take more Depakine than you should

If you take more Depakine than you should Talk to your doctor or go to the emergency room immediately. If you forget to take Depakine Do not take a double dose to make up for a foreotten dose. If you stop taking Depakine

you sup taking begalane to not stop taking Depalane without asking your doctor's advice. Treatment should be stopped gradually. If you stop taking Depalane uddenly of before your doctor asks you to you will be emoved to a higher risk of services.

4. POSSIBLE SIDE EFFECTS

Publisms with balance and condination, leeking of leiburgs or poozer alentness, combined with vorning. This may be due to an increase in the annual of ammonium in your bood.

Increase manages hepatitiss or parness damage (pastrocatios, which may be serious and life threatening, and that can start suddenly with faithere. Loss of another: chearboom, composition, success continue and storanch nature.

anger, this layesus, seasons, or some of mind to extend the season of the life of the life

that can populy spread to the entire body and be life-threatening lightly specimes. Severa-jobious spackmed, there populs side effects and motor development (disorders (see section 2. Preparacy, breast-leeding and fertility). I the disorder polyments (innectable) of any of the following side effects become serious or last more than a few days. You may need ungest medical beatment:

n Imay affect up to 1 in 10 people):

y unsurers, on, aggressiveness, agitation, attention deficit disorders, hallucinations (seeing, hearing or feeling things that are not there), ramusal disorders (a group of symptoms such as tremor, stiffness of the limbs and difficulty walking)*,

 leakage of urine (urinary incontinence).
 rapid and uncontrollable eye movements. r recurriguos, o gum disorders (gingixal problems), in particular an increase in gum size (gingixal hypertrophy), o gainful, swollen mouth, mouth ulcers and burnine sensation in the mouth (stomatiss).

loss, strual problems (irregular menstruation),

 nall and nail bed disorders.
 decrease in the number of platelets (thrombocytopenia), decrease in the number of red blood cells (anaemia).
 decrease in the amount of sodium in the blood (hippordineema, syndrome of inappropriate ambdurets horihor Uncommon (may affect up to 1 in 100 people):

"Impaired actives that may go as far as transent coma, regressing after the dose is decreased or the treatment stopped,

"difficulty confinating poverments,"

officials coordinating invienments, reversible padicinsorism⁴, sensation of numbers or pricibing in the hands and feet, subcommal hair tenture; change in hair colour, abnormal hair growth, rash or hires on the kish, each or hires on the kish, each subject to the kish, each part of the

- seeling of the objectives (seeting), - amounthous land or institutal period), - wassing and increased frequency of consistons, onsed of a different type of consistent, - wassing and increased frequency of consistent, onset of the protective membranes of the large [plexical efficient, - because in the numbers of all billion of ext. white blood eds., and spatiets [partspecial], - decrease in the numbers of all billion of ext. white blood eds., and spatiets [partspecial], - and the numbers of t

 Bood vector inflammation.
 Bare Jiany affect up to 1 in 1,000 people;
 Sand Final parties up to 1 in 1,000 people;
 Sand Felling Adouters, generally neversible at least 3 months after treatment is discontinued, and possibly reversible after a reduction in the dose. On not step your teatment without first taking to your declar. and leftall disolets, pensals, resolid, at least 3 months after teatment is discontinued, an interface of the discontinued and interface of the discontinued and interface, and a superior of the course; playing state and interface, and a superior activity, learning disabilities, a behavior and disturbances, increased psychonotor activity, learning disabilities, and interface psychonotory and interface of the disabilities, and interface psychonic plays erythematosus, decreased through gland activity inpolythroutism; in muscle parameter sealless shift any leverous plantation of the disabilities.

cases of bone disorders have been reported, such as the bones becoming more fragile (osleopenia), a decrease in bone mass (osleopenis) and features, consult your dector or pharmaces! If you are on long-term treatment with an arrisepileptic medicine, if you have a histay of osleopencos or if you are labling confocience.

tary leakage of urine, usually at night (erunesis),

Atters damage jobers batter, behölmist skild resphilist with of man market as decreased unine output,
 arroare in the size of with blood cells journation journal extense in the number of white blood cells journation journal, and output of extensed production of blood cells journation journal, advantage journation of blood cells journation, deserved during blood cells, symmetries resided by leve and difficult breathing.
 cereziese production of force, and difficult breathing.
 cereziese production of tours, advantage lound production of blood cells imprecise in PIR, increase in polongation of activated partial

to the gradual onset of memory and mental capacity disorders (cognitive disorders, dementia)*. These problems decrease a few weeks to a few months after treatment is discriptional. requency not known decreased carmitine level (observed in blood or muscle tests).

not stop your freatment without first talking to your doct ated with brain imaging signs (cerebral atrophy). Additional side effects in children dditional side effects in children ome side effects of valpnaate occur more frequently in children or are more serious than in adults. These lead to liver damage, filarimajon of the parioresi parioretalisis, aggression, agitation, disturbance in attention, abnormal behaviour, hiperactivity, and

earning assources.

Reporting of side effects

This includes any possible side effects not listed in this leaflet.

This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE DEPAKINE ep into mecione out or the signi and reach of crivaters. The below 30°C I not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. ont throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer on these measures will help notified the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION What Depakine 200 mg/ml oral solution contains

ml of solution is equivalent to 200 mg of sodium valproate. The other investigants are: orea, subsolum nydroude solution and purified water. What Depakine 200 mg/ml oral solution looks like and contents of the pack Into interiorie is supplied as an oral solution. 40 ml both Marketing Authorisation Holder Sanofi Winthrop Industrie

82, Avenue Raspail 94250 Gentilly Manufacturer nofi Winthrop Industrie -36. Avenue Gustave Eiffel

compared a committed answer. It can expension of a sea and increase a second and in the leading of destrict all and in the part of the committee of the committ GENERAL ADVICE

Fillerso is a neumbnizal disease. It is an expression of acute and temporary abnormal function of electrical activity in the brain, resulting

the time of the doses treatment duration, generally long-term,
lifestyle recommendations: avoid overwork, lack of sleep, and alcohol. ment, can cause seizures to recur. DO NOT FORGET TO TAKE YOUR MEDICINE WITH YOU IF YOU TRAVEL