

GAPP – GAbapentin in Paediatric Pain

PAINAWAY TO THE RESCUE!



GABA-1 7-11 years

IN DOCTOR PAINAWAY'S STUDY...

HIYA. MY NAME IS DOCTOR PAINAWAY.
I'M RESEARCHING HOW WE CAN DRIVE AWAY
THE PAIN THAT **YOUNG PEOPLE**
LIKE YOU MIGHT FEEL.

THIS IS MY ASSISTANT BUNSEN,
A MAN OF FEW WORDS.

JUST ONE, IN FACT.

GABA.

BUNSEN SAYS "HI".



NORMALLY, OUR BODY FEELS PAIN
FOR A **SIMPLE REASON...**



AS I BRING MY HAND
CLOSE TO THE FLAME...

OUCH! SEE? OUR BODY QUICKLY
REACTS TO PREVENT IT
GETTING TOO HURT.



BUT WHEN THE PAIN IS TOO
STRONG AND DOESN'T GO AWAY,
WE NEED TO **ACT.**



WHICH IS
WHY WE STARTED
TO USE THIS
MEDICINE.



GABAAAA!

OH, DEAR!



SORRY, BUNSEN.
THIS MEDICINE
ONLY WORKS IF YOU'VE
BEEN IN PAIN FOR
A LONG TIME.

GABAAAA!



YOU'LL BE FINE SOON, DON'T WORRY.

GABA GABA.

BUNSEN
SAYS
"THANK
YOU".

THIS IS WHAT HAPPENS WHEN THE MEDICINE IS TAKING THE PAIN AWAY

THE MEDICINE HAS BEEN USED A LOT, BUT WE DON'T YET KNOW IF IT WILL WORK FOR **CHILDREN LIKE YOU.**

WHICH IS WHY WE'RE ASKING YOU TO TAKE PART TO THE GABA STUDY.

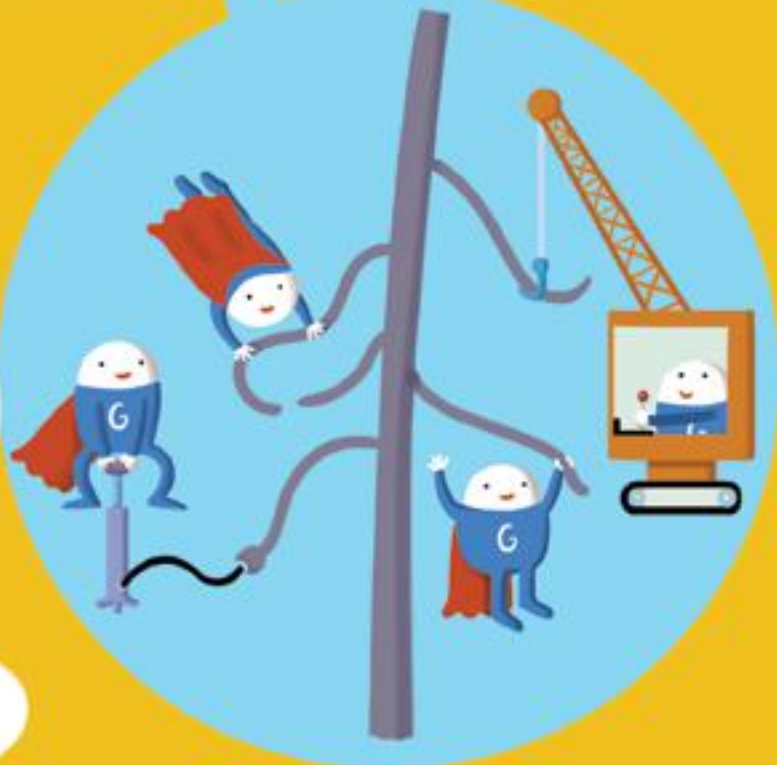
GABA
GABA?



YOU DON'T?
OH, DEAR...

THE **GABA** STUDY IS JUST A WAY TO UNDERSTAND HOW WELL THE MEDICINE WORKS WITH CHILDREN.

HERE,
LET ME SHOW YOU.



A GROUP OF CHILDREN WILL TAKE SOME **SYRUP** AND A FEW **DROPS** **THREE TIMES A DAY.**



EVERY DAY, THEY WILL TELL THEIR PARENTS **HOW STRONG** THEIR PAIN IS. THIS WILL LET THE DOCTORS KNOW IF THE MEDICINE IS WORKING OR IF THEY NEED MORE.

WE REALLY HOPE THE PAIN WILL GET BETTER, BUT YOUR BODY **TAKES TIME** TO REACT TO THE MEDICINE SO IT CAN TAKE A **COUPLE OF WEEKS.**



SO IT'S IMPORTANT TO ALWAYS **TELL THE TRUTH** ABOUT THE PAIN YOU'RE FEELING.



BUT HOW DO YOU
MEASURE PAIN?

GOOD QUESTION, YOUNG LADY!

YOU CAN MEASURE PAIN BY **PUTTING A CROSS** ON ONE OF THESE LITTLE FACES.



BUNSEN WILL SHOW YOU HOW THIS WORKS.

ARE YOU SURE YOU WANT TO DO THIS, BUNSEN?

GABA GABA!

YOU'RE SO BRAVE...



IF YOU ARE A BIT OLDER, YOU CAN ALSO MEASURE PAIN BY SAYING HOW MUCH IT HURTS **FROM 0 TO 10**.

0 MEANS YOU'RE FEELING **GREAT**, AND **10** MEANS IT HURTS AN **AWFUL LOT**.



WHAT ELSE WILL HAPPEN IN THE STUDY?

THE STUDY WILL LAST BETWEEN **18 TO 22 WEEKS**.
YOU WILL VISIT THE DOCTOR **12 TIMES**,
EITHER AT THE HOSPITAL OR OVER THE PHONE.

1

THE **FIRST PART** OF THE STUDY WILL BE **1 TO 2 WEEKS** LONG, WITH **2 VISITS**.

ON YOUR FIRST VISIT, THE DOCTOR WILL GIVE YOU A CHECK UP, TAKE SOME OF YOUR BLOOD AND USE A LITTLE MACHINE TO FIND OUT HOW WELL YOUR HEART IS WORKING.

FOR 3 DAYS AFTER THAT YOU WON'T TAKE ANY MEDICINE, EXCEPT FOR FAST PAIN RELIEF MEDICINES IF YOU REALLY NEED THEM.



2

THEN THE **SECOND PART** OF THE STUDY WILL BE **15 WEEKS LONG**, WITH **8 VISITS**.

THE DOCTOR WILL GIVE YOU THE **DROPS** AND **SYRUP** TO TAKE THREE TIMES A DAY.

THE DOCTOR WILL ALSO TAKE SOME OF YOUR BLOOD ONCE OR TWICE. ON ONE VISIT, YOU WILL SPEND 4-5 HOURS IN THE HOSPITAL, SO HE WILL TAKE BLOOD OVER A LONGER PERIOD.



BUT IT ONLY STINGS FOR A MOMENT!



3

THE THIRD AND LAST PART OF THE STUDY WILL BE FROM **1 TO 5 WEEKS LONG**, WITH **2 MORE VISITS**.

YOU WILL TAKE LESS AND LESS OF THE MEDICINE AS YOU APPROACH THE END OF THE STUDY.



YOUR DOCTORS WILL MAKE SURE EVERYTHING IS OKAY AND ASK YOU **HOW YOU FEEL**.

IT'S IMPORTANT TO TELL THEM THE **TRUTH**. ISN'T IT, BUNSEN?

GABA GABA
GABA GABA
GABA...

I REST MY CASE.



THESE ARE YOUR 12 VISITS OVER THE 18-22 WEEKS OF THE STUDY.

ARE YOU READY?

SET?

GO!

THE RULES OF OUR STUDY:

- 94 CHILDREN, UNDER 18 YEARS OF AGE
- 18-22 WEEKS IN LENGTH
- 3 DAYS WITH ONLY MEDICINES FOR FAST PAIN RELIEF
- 15-19 WEEKS TAKING THE STUDY MEDICINE
- 2 OR 3 BLOOD SAMPLES



GABA!

BUNSEN SAYS YOUR DOCTOR MIGHT VISIT YOU A FEW EXTRA TIMES.

WELL DONE!

CHECK-UP AT HOSPITAL



VISIT OVER THE PHONE



ECG (ELECTROCARDIOGRAM)



BLOOD SAMPLE



AND THAT THIS IS PERFECTLY **NORMAL**.

WHAT TESTS WILL YOU HAVE TO DO?



YOUR DOCTOR
WILL EXAMINE YOU
TO CHECK YOU'RE OKAY.



YOUR DOCTOR
WILL TAKE SOME
OF YOUR BLOOD
2 OR 3 TIMES.



YOU MAY FEEL **LESS PAIN** THAN BEFORE.

WHICH MEANS YOU CAN HAVE MORE FUN. MORE GAMES, MORE SCHOOL, MORE EVERYTHING.

WHY SHOULD I TAKE PART?

YOU MAY HAVE **FEWER PROBLEMS** THAN WITH YOUR CURRENT MEDICINES.

YOU MAY **HELP OTHER CHILDREN** WHO ALSO NEED TO TAKE MEDICINE FOR PAIN.

YOUR DOCTOR WILL ALWAYS KEEP AN EYE ON YOU AND MAKE SURE THAT THE STUDY IS NOT DANGEROUS. ALWAYS TELL YOUR PARENTS OR YOUR DOCTOR **HOW YOU ARE FEELING**, SO THAT WE CAN **HELP**.

YOU WILL NEED TO **GO TO THE HOSPITAL** 8 TIMES, HAVE A **FEW TESTS** AND TAKE YOUR **MEDICINES**.

AND WHAT ARE THE DOWNSIDES?

IF YOU FEEL TOO MUCH PAIN, YOUR DOCTORS MAY GIVE YOU MORE MEDICINE. BUT IF YOU TAKE A LOT OF THE MEDICINE, YOU MAY GET WHAT WE CALL **SIDE EFFECTS**.

WHAT ARE THESE SIDE EFFECTS?



THAT'S WHY IT'S **IMPORTANT** TO ALWAYS TRUTHFULLY TELL US HOW YOU FEEL.

IF YOU FEEL **ANYTHING STRANGE** HAPPENING, **TELL YOUR PARENTS** OR LET **YOUR DOCTOR** KNOW STRAIGHT AWAY.

YOUR DOCTOR WILL TELL YOU **WHAT TO DO.**

ASK AWAY TO DOCTOR PAINAWAY

DO I HAVE TO TAKE PART TO THE STUDY?

GOODNESS, **NO!**
YOU CAN DO AS YOU WISH.

IT'S NORMAL TO HAVE
THE SIDE EFFECTS?

ABSOLUTELY. SOME PEOPLE
HAVE THEM,
AND SOME PEOPLE DON'T.

BUT IF YOU ARE WORRIED,
REMEMBER YOUR DOCTOR
WILL ALWAYS BE KEEPING
AN EYE ON YOU.

OH, DEAR...

WHO WILL KNOW
I'M TAKING PART?

ONLY **YOU**, YOUR **PARENTS**
AND YOUR **DOCTOR**.

WHAT IF I CHANGE MY MIND
DURING THE STUDY?

YOU CAN **LEAVE** AT ANY TIME.
YOUR DOCTOR WILL **CONTINUE**
HELPING YOU AS HE DID BEFORE.

THE CHOICE IS YOURS TO MAKE.

GABAAAA!

GAPP – GAbapentin in Paediatric Pain

COORDINATOR

Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF)

GABA-1 Clinical Trial

EudraCT Number: 2014-004851-30

SPONSOR

PHArmsaceutical Research Management SRL (PHARM)

Randomized, double-blind, double-dummy, active controlled, multicentre, non-inferiority phase III study to compare the pharmacokinetic, efficacy and safety of gabapentin liquid formulation to tramadol in children from 3 months to less than 18 years of age experiencing moderate to severe chronic neuropathic or mixed pain.

The **Patient Advisory Board**, established in the framework of GAPP Project and coordinated by Rebecca Lundin (PENTA Foundation), has contributed to the **scientific contents**.

COMMUNICATION TEAM

Booklet production coordinator: Maria Cavallo (CVBF)

Content Editor: Leonardo Rizzi

Illustrations and graphics: Piero Corva

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www.pediatricpain.eu

info@pediatricpain.eu